

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: PHARMACEUTICAL INDUSTRY	)	MDL DOCKET NO. 1456
AVERAGE WHOLESALE PRICE	)	
LITIGATION	)	Master File No. 01-CV-12257
	)	Subcategory Case No. 06-CV-11337
	)	
THIS DOCUMENT RELATES TO:	)	Judge Patti B. Saris
	)	
<i>U.S. ex rel. Ven-A-Care of the Florida Keys,</i>	)	Magistrate Judge Marianne B. Bowler
<i>Inc. v. Abbott Laboratories, Inc., et al., No.</i>	)	
06-CV-11337-PBS	)	
	)	
<i>U.S. ex rel. Ven-A-Care of the Florida Keys,</i>	)	
<i>Inc. v. Dey, Inc., et al., No. 05-CV-11084-</i>	)	
PBS; and	)	
	)	
<i>U.S. ex rel. Ven-A-Care of the Florida Keys,</i>	)	
<i>Inc. v. Boehringer Ingelheim Corp. et al.,</i>	)	
No. 07-CV-10248-PBS	)	

**DEFENDANTS ABBOTT LABORATORIES, INC.,  
DEY, INC., DEY, L.P., DEY L.P., INC., AND  
BOEHRINGER INGELHEIM ROXANE, INC. AND ROXANE LABORATORIES, INC.'S  
COMBINED LOCAL RULE 56.1 STATEMENT OF  
ADDITIONAL MATERIAL FACTS PERTINENT TO  
THE UNITED STATES' MOTIONS FOR  
PARTIAL SUMMARY JUDGMENT AGAINST DEFENDANTS**

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**PRELIMINARY STATEMENT**

Pursuant to the Federal Rule of Civil Procedure 56 and Local Rule 56.1, Defendants Abbott Laboratories Inc. (“Abbott”), Dey, Inc., Dey, L.P., and Dey, L.P., Inc. (“Dey”) and Boehringer Ingelheim Roxane, Inc. (f/k/a Roxane Laboratories, Inc.) (“Roxane”) (collectively, “Defendants”) submit the following other additional material facts that are necessary for this Court to determine the United States’ individual motions for partial summary judgment against Defendants.

In addition to this filing, Defendants have filed, concurrently herewith, a combined response to the United States’ Local Rule 56.1 Statement of Undisputed Material Facts Common to All Defendants, as well as responses and additional material facts pertinent to the United States’ motions for partial summary judgment and Local Rule 56.1 statements of undisputed facts filed in the individual cases.

**I. EXPECTATIONS REGARDING THE PRICING BEHAVIOR OF GENERIC DRUGS**

1. Numerous state officials testified that they understood that compendia AWP's were not a reliable source of market prices for generic drugs, and that spreads were much greater for generic drugs than for brand drugs. For example:

(a) Leo Sullivan, the former Director of Pharmacy Services for Tennessee Medicaid from 1989 to 2004, testified:

Q. Did you believe that you could shave 20, 30 percent off of it and get to a reliable number of what pharmacies and physicians actually paid for drugs?

A. Well, it would, it would depend on -- I mean, are we talking brand or generic?

Q. Both right now. Would you draw a distinction?

A. Oh, yeah. Yeah.

Q. All right.

A. The generic drugs, you know, you could pay AWP minus 80 percent and still the pharmacist make money for some, I assume. But AWP minus 25 might be below cost for a brand name drug for a rural pharmacy that has a very small volume. Okay? So there is, there is a difference between brand and generic. In Tennessee, it wasn't as pronounced because, you know, what I did as part of my job, as soon as a drug became multi-source, and after OBRA '90, as soon as that drug, the multi-source version of a drug was cheaper than the brand name net-net of Medicaid rebates, we MACed it. So AWP wasn't an issue on the generic side.

Q. And why did you --

A. But to say 20-30 percent, use that number, you would have to distinguish between brand and generic.

Q. Would it be fair to say, Mr. Sullivan, that during the entirety of the time that you were the director of pharmacy services for the State of Tennessee that you knew that the AWP's and the Red Book and Blue Book were a particularly unreliable source for actual acquisition costs for generic drugs.

MR. DRAYCOTT: Objection.

A. That's true.

BY MR. TORBORG:

Q. And from your interactions with other state pharmacy administrators, do you believe that they knew that as well?

MR. DRAYCOTT: Objection.

A. Same answer as before. I don't remember ever discussing it. I think it's safe to assume that, though. I would assume that.

BY MR. TORBORG:

Q. Okay. And why, why would you assume that?

A. Because it's, it's such a known fact within the industry.

(3/12/08 Sullivan 100:13-102:18, Ex. 1.)<sup>1</sup>

(b) Robert Reid, former Administrator of the Ohio Medicaid Pharmacy

Service Unit, testified:

“Question: And why did you --“ then the answer, “But to say 20, 30 percent, use that number, you would have to distinguish between brand and generic.” Do you see that?

A. I got it.

Q. Do you have an understanding of what his testimony was there?

MS. GEOPPINGER: Object to the form of the question. You can answer if you know.

A. I can say that I don't know what -- where Mr. Sullivan was coming from, but I would say generally that I might have responded to those questions in the same manner. He's making a clear distinction between trade name drugs and generic drugs, and that is true.

Q. That's something that you understood as well?

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<sup>1</sup> Each of the exhibits cited in this document (“Ex.”) are attached to the Declaration of David S. Torborg filed concurrently with this motion.

A. Yes.

Q. That discounts were higher on the generic side than they were on the brand name side?

A. The representation of AWP, the difference between AWP and AAC was greater on the generic side than it was on the trade name side.

Q. That's something that you were aware of?

A. Yes, I was aware of that.

(12/15/08 Reid Dep. 109:7:110:13, Ex. 2.)

(c) Benny Ridout, former Medicaid Pharmacy Director for North Carolina, testified:

Q. When did you get these updates from the generic manufacturers that you were referring to?

A. They were wholesalers, mostly out of Florida, wholesalers that were trying, in other words, they had me listed as a pharmacy, I guess as a position, or they wanted to include me on the mailing list because they felt like I wanted to know the price of drugs or something.

Q. When did you receive these mailings from wholesalers showing the discrepancies between –

A. And some were drug manufacturers.

Q. And manufacturers. The manufacturers and the wholesalers sent you these mailings. Do you recall when you received them?

A. All through my career.

Q. So the entire 29 years?

A. Well, no, originally I didn't get them, I guess before '92, probably in the '80s, probably the '80s I started receiving them.

Q. What did these mailings show you about the difference between average wholesale price, direct price and the selling price for these generic drugs?

A. What was really amazing to me is what they would show is maybe the AWP would be let's say \$100. The actual selling price may be \$30. That's when I really, really -- and all the pharmacists start thinking about gosh, if I'm paying for this drug it had the AWP there and that's what I'm basing my price on, and I got \$100 in the computer and they are selling it over here, you know, for this price, there's a big range in there, and we started looking at that range.

(12/5/2008 Ridout Dep. at 36:6-37:19, Ex. 3.)

Q. Oh, I'm talking just about what you observed from the fliers that you received that would have an average wholesale price listed, and that would list what the actual or what the offered price was from that wholesaler, the difference between those two numbers, do you understand?

A. The brands always had less markup on them than the generics.

(*Id.* at 50:4-11.) Ridout also testified:

Q. And in your experience, if a drug had more competition, do you see greater differences between the AWP and what you can buy the drug for?

MS. YAVELBERG: Objection to form.

MS. HAYES: Objection to form.

A. You know, once again, like I said, I made that statement about competition or market share, I think I used, if it was, I guess, market share was up, down in that particular one or like it was competition, the spread wouldn't be as much, it would be closer to the AWP rather than such a widespread. The ones that maybe they got out and there's only two companies that had that product on the market instead of four or five, the spread would be greater, and if you remember when I authorized generic or either the generics the first company bring the drug to the market, they get exclusivity for six months to where they price it, nobody else can copy that, generic companies. And usually that first six months the generic price is very close to the brand name price. Then after that six months is over, other drug companies can enter the market for that product, and that's when you see the prices start going down, when the competition comes in.

(*Id.* at 54:4-55:15) Ridout also acknowledged that spreads were being paid for infusion products:

Q. Do you recall whether it was similarly common knowledge that infusion products had spreads?

MS. YAVELBERG: Objection, form.

MS. HAYES: Objection, form.

A. We had no idea what the specialty pharmacists were paying for that drug, what kind of deals they struck with the manufacturers, but it was of their opinion of us that there was some kind of spread in there because of what they were able to do that a regular pharmacist couldn't do at AWP. You see, we still paid at AWP.

Q. What do you mean what they could do that other pharmacists couldn't?

A. Infusion drugs is a whole lot more than just putting a pill in a bottle. You got to prepare. In fact, the pharmacists wanted a special fee to do this under-the-hood preparation, you know, also injection takes longer, you got to have syringe and all the stuff to do that. Of course they were shipping that on top of the cost to ship the product. So if you add up all that extra cost in a regular pharmacy or regular pills, you know, you think well, how in the world can they afford to do this and accept that same price?

Q. What was your conclusion?

A. That somehow they were getting some kind of special deal back or discount from the manufacturers to be able to do it or something. That was just my own personal feeling. How did they do it?

Q. And the significance of their ability to get special deals would be that they could make profit on the drug ingredient cost, right?

MS. YAVELBERG: Objection to form.

MS. HAYES: Objection to form.

A. I have no idea what profit they made or what they were doing. I just know that nobody does anything for a loss. You wouldn't stay in business.

(*Id.* at 62:16-64:12)

(d) Sandra Kramer, former Policy Analyst for Michigan Medicaid, testified:

Q. Okay. Did you understand that the spread for generics was larger than the spread for brand name drugs?

A. Yes.

Q. Okay. What was that understanding based upon?

A. Probably at the time that I was at Michigan Medicaid, input from the pharmacists.

Q. So you would discuss AWP with pharmacists?

A. Actually, I—my responsibility included, as we mentioned before, setting the MACs.

\* \* \*

Q. And what was the source of information for your statement that AWP's are generally inflated significantly over pharmacy purchase costs?

A. As I mentioned, setting the maximum allowable cost prices and comparing those to the AWP that was—I guess we're using the term significant spread. . . .

(3/25/08 Kramer Dep. at 84:14-85:20, Ex. 4; *see also* Ex. 5 (Abbott Ex. 655).)

\* \* \*

Q. Okay. The next paragraph you say: "As an example, I have attached the direct (or acquisition cost) and AWP for several new products from a major generic company. The price differentials are enormous with AWP ranging from 13 percent to 500 percent above acquisition cost!!!"

With the three exclamations, were you also trying to get his attention?

MR. HENDERSON: Objection.

A. I think it speaks for itself.

BY MR. GABEL:

Q. Okay. Fair enough. You state: "The price differentials are enormous—" well, actually, strike that. It's fair to say that as early as 1992 you realized that in some instances AWP's were upwards of 500 percent above acquisition costs?

A. For the generic.

Q. For the generic specifically?

A. That's what I'm referring to here.

(*Id.* at 93:5-94:2, Ex. 4; *see also* Ex. 6 (Abbott Ex. 656).)

(e) Nancy Nesser, Pharmacy Director of Oklahoma Health Care Authority, testified:

Q. And in '95, '96 what was your understanding of the difference between AWP and actual acquisition costs for generic drugs?

A. That sometimes there was a wide difference. Not always.

Q. Can you describe what you mean by "wide difference"?

A. Just that it was – it was variable. It wasn't a standard. It wasn't, like, with the brand name where you could – you can see it's consistent. If you pulled two manufacturers brand-name products off the shelf, the markup is going to be about the same. If you pulled two – even of the same generic drug, the – there's no consistency between the AWP and the acquisition.

(12/12/08 Nesser Dep. at 54:8-22, Ex. 7.)

(f) David Campana, Alaska's Director of Pharmacy, testified:

Q. Now, we have spoken about benchmark prices. Did you come to an understanding, sir, at any point during this time period, from 1960s right up until 1990, whether the differential between the benchmark price and the actual price being paid by a pharmacy for drugs was greater for generic drugs than it was for branded drugs?

A. Yes, I've come across that information.

Q. What is your understanding of what happens in that area?

MR. BURNHAM: During what time period?

BY MR. MANGI:

Q. Let's start with -- well, back up. When you say you have come across that information, when did you first become aware of that phenomenon?

A. I don't remember time period.

Q. Would it be fair to say it's a long time ago?

A. Yeah.

MR. HENDERSON: Objection.

BY MR. MANGI:

Q. In other words, would you say that's -- perhaps bucketed by decades, would it be fair to say that's perhaps sometime in the '60s or the '70s as opposed to the '80s or the '90s?

A. It's hard to say when I became aware of that.

Q. Well, would it be fair to say it was before 1990?

A. Yes.

Q. And what generally did you become aware of, sir?

A. That the net cost to the pharmacy for generics that have been out for a long time was very low compared to the benchmark.

Q. And benchmark that we are talking about here, so the record is clear, is AWP, correct?

A. Correct.

Q. So in other words, at some point prior to 1990, you became aware that when generics come into the market, there is increased competition, correct?

MR. BURNHAM: Objection, foundation.

THE WITNESS: There is increased competition the longer the generic is available.

BY MR. MANGI:

Q. And one manner in which that increased competition manifests itself in the market is increasing discounts, correct?

MR. BURNHAM: Objection, foundation.

THE WITNESS: Yes.

BY MR. MANGI:

Q. In other words, it's price competition between the different manufacturers of the generic product?

A. Yes.

Q. And as a result of that price competition, there becomes a greater differential between that benchmark AWP and the actual price that pharmacies are paying than exists for branded drugs, correct?

MR. HENDERSON: Objection.

THE WITNESS: Yes, there is a greater differential.

BY MR. MANGI:

Q. And indeed, the extent of that differential will depend on the number of generics and the extent of competition, correct?

MR. HENDERSON: Objection.

THE WITNESS: The number of manufacturers making that drug.

BY MR. MANGI:

Q. Absolutely. And to put it another way, then, if there is just one generic manufacturer that's in the market competing only with the manufacturer of the brand, that's a different situation from where, let's say, there are five generic manufacturers all putting the same drug in the marketplace, correct?

A. Correct.

Q. In the latter situation where you have many manufacturers selling what's essentially the same drug, there will be a greater degree of competition because they are all competing with each other for the same market space, correct?

A. Correct.

Q. And in that situation, there will be more discounts and a greater differential between the published AWP and the actual price pharmacies are paying than there would be where there is little competition, correct?

MR. BURNHAM: Objection, foundation.

MR. HENDERSON: Objection.

THE WITNESS: Yes.

BY MR. MANGI:

Q. And is it fair to say, sir, that the extent of the differential, therefore, is a product of and a function of marketplace competition?

MR. BURNHAM: Same objection.

THE WITNESS: Yes.

BY MR. MANGI:

Q. Is it fair to say, sir, that there is, therefore, no predictable relationship between the AWP of a generic drug and the actual price that a pharmacy is paying to purchase that generic drug?

MR. BURNHAM: Objection, form.

MR. HENDERSON: Objection.

THE WITNESS: I have never seen a formula to exactly determine that.

BY MR. MANGI:

Q. In other words, you understand that it's just something that's going to vary for generic drugs depending on the extent of competition, correct?

MR. BURNHAM: Objection.

THE WITNESS: Yes.

BY MR. MANGI:

Q. And you have understood that going back a number of years. You are not sure when exactly, but certainly since before 1990 you have had that understanding, correct?

A. Yes.

(8/19/08 Campana Dep. at 93:15-99:7, Ex. 8.)

\* \* \*

Q. When did you first learn of an AWP -- strike that. When did you first learn of drugs that pharmacies could purchase for less than half of the published AWP?

A. I'm not sure where I picked that up, but for generic drugs there was information that you could purchase those at a -- at a very small rate compared to AWP.

Q. And is that something recent?

A. I remember some of that information just based on what was provided back when I was working in retail.

(8/20/08 Campana Dep. at 759:13-760:2, Ex. 9.) Mr. Campana also testified that, in the early 1990s, Alaska compared URAs for generic drugs to AWP's and recognized that "there was a huge difference" between the prices. (*Id.* at 721:8-14.)

(g) Suzette Bridges, Administrator of the Arkansas Medicaid Prescription Drug Program, testified:

Q. And based on what we've seen, you would expect that the discounts available for pharmacies, when purchasing generic drugs, are typically greater than the discounts when purchasing branded drug?

MS. OBEREMBT: Objection.

A. I can only make that assumption based on the survey findings. The survey findings generally show that -- and I'd have to look at the survey again, that the variance on brand is not as great on the variance on generics. I mean, that's common knowledge. I'd guess you'd say.

(12/11/08 Bridges Dep. at 358:20-359:10, Ex. 10.) Bridges also testified that invoice pricing information that Arkansas received from pharmacies prices much lower than AWP. (*Id.* at 250:9-18.)

(h) Allen D. Chapman, former Pharmacy Program Manager in Colorado, testified:

Q: Now I would like you to look at the last page of this letter. And if you look at the second-to-the-last paragraph, second sentence, it says, "For multiple-source drugs, I would make extensive use of state upper limits as neither the FUL or AWP mean anything for generic drugs."

Do you agree with Mr. Hazelwood's statement that the AWP does not mean anything for generic drugs?

A: I guess my comment was there's probably more of a variation between AWP and actual cost with generic than there are the other.

Q. (BY MR. KATZ) "The other" would be brand?

A. Brand -- no -- the other would be brand, right, . . . .

(12/15/08 Chapman Dep. at 107:9-108:4, Ex. 11.)

\* \* \*

Q. (BY MR. BERLIN) At the time that you were working for the hospital, was it your view that AWP was essentially a list price and that there were discounts below it for different providers?

A. I guess to probably characterize my thought of that, it was something if you looked up a product in the Red Book or the Blue Book, whatever it was, you saw a price there, but it had no relationship to the price that we might be paying in our marketplace.

(*Id.* at 222:22-223:10.)

(i) Jerry Wells, former Pharmacy Program Manager in Florida, testified:

Q. And for innovator multisource products, what was the discount they were able to receive?

A. It was 43.41 percent.

Q. What are innovator multisource products?

A. That is a product whose patent has expired but is still marketed by the original NDA applicant.

Q. Do you have an expectation for what the discounts from AWP would be for noninnovator multisource products?

A. Because those manufacturers and suppliers tend to overstate their AWP's, you can see 80 or 90 percent in some cases.

Q. And you've known that since at least 1995, right?

MS. ST. PETER-GRIFFITH: Object to the form.

MS. WALLACE: Objection to form.

MR. BREEN: Objection, form.

THE WITNESS: I don't know that I know that to that extent in 1995. Certainly in 2001 I knew that.

BY MR. COOK:

Q. The sentence after you discussed the discounts from single source brands and innovator multisource products reads, quote, "These are predictable, confirm the ability of closed shop pharmacies to negotiate pricing concessions from pharmaceutical manufacturers that may not be available to community-based pharmacies," closed quote. Do you see that?

A. Yes.

Q. That was true in 2001, correct?

MS. ST. PETER-GRIFFITH: Object to form.

MS. WALLACE: Objection, form.

THE WITNESS: I believed it to be true. That's why I put it in the letter.

BY MR. COOK:

Q. And that was the same phenomenon that you had observed in 1998 with the Legislative Proposal Analysis we looked at, right?

MS. ST. PETER-GRIFFITH: Object to the form.

THE WITNESS: That was a little different issue, but it would still apply.

BY MR. COOK:

Q. And that was the same issues that you saw discussed in response to the 1996 Florida-specific report about pricing for IV drugs and IV fluids, correct?

MS. ST. PETER-GRIFFITH: Object to the form.

THE WITNESS: That was a presumption that we had made in the 1996 period.

BY MR. COOK:

Q. Other than the meeting in Richmond in September of 1995, have you had discussions with anybody from HCFA about the deeper level of discounts that are available to purchasers of IV fluids and IV drugs via the pharmacy market?

A. Very likely I have.

(12/15/08 Wells Dep. at 206:2-208:21, Ex. 12.)

\* \* \*

Q. What was your understanding of what discounts -- I'm sorry -- pharmacy providers were paying? And let me break that into two questions. What was your understanding of what pharmacy providers were paying for single source brand drugs, and, then secondly, what was your understanding of what pharmacy providers were paying for multisource generics?

A. Single source brand drugs were typically at 14 to 15 or even 16 percent discount below the published AWP at that time. And generic products were all over the map; depended on who you bought them from. That was before, I think, generic manufacturers had really started jacking up their published AWP's. So, you know, some were fairly accurate and others were inflated to greater or lesser extents.

(*Id.* at 266:9-267:4.)

Q. In the article, there are quotes referring to AWP as, quote, "meaningless" and, quote, "a joke."

MS. ST. PETER-GRIFFITH: Object to form.

MR. BREEN: Objection to form.

BY MR. COOK:

Q. Would that be a better characterization for AWP with respect to generics?

MS. ST. PETER-GRIFFITH: Object to form.

MS. WALLACE: Object to form.

THE WITNESS: I don't know that that article said that. There was a letter from Ven-a-Care that mentioned that AWP was a joke.

AWP was a pricing reference point that is a reasonable indicator of approximate cost for brand name drugs. It is no longer a reasonable indicator for generic drugs and I don't know when that diversion occurred. At one point it probably was a reasonable indicator for generic drugs.

BY MR. COOK:

Q. Certainly by 1990 it was no longer a reasonable indicator of price for generic drugs, correct?

MS. WALLACE: Object to form.

MS. ST. PETER-GRIFFITH: Object to the form.

MR. BREEN: Object to form.

THE WITNESS: I think that by 1990 that would be a valid statement.

(*Id.* at 339:13-341:2.)

(j) A 1994 document from Illinois Medicaid, which discussed a proposal to change the reimbursement methodology for prescription drugs, stated: "AWP has become virtually meaningless as a real number, particularly for multi-source drugs;" (Ex. 13 (Roxane Ex. IL 5).) A 1995 document from Illinois Medicaid referred to AWP as "most meaningless for generic drugs." (Ex. 14 (Roxane Ex. IL 7).) In an October 4, 1995 response letter to a survey from South Dakota Medicaid regarding the relationship between AWP and pharmacy cost, Illinois Medicaid stated that neither "the FUL or AWP mean anything for generic drugs." (Ex. 15 (Roxane Ex. IL 8).)

(k) James Parker, Illinois Medicaid Deputy Administrator, testified:

Q. And that methodology, the methodology of using AWP, remained in place up until December 2000?

A. Correct.

Q. And then for a six-month period, the methodology also incorporated WAC?

A. Correct.

Q. Then the system moved back to the use of just AWP?

A. Correct.

Q. And in so doing, Illinois Department of Public Aid was aware that AWP as early as 1995 had become “most meaningless for generic drugs”?

A. Yes.

(11/18/08 Parker Dep. 202:8-21, Ex. 16.)

(l) Ron Gottrich, former Consultant Pharmacist with the Illinois Department of Public Aid, signed an affidavit that included the following statements:

- “During the entirety of my time at IDPH, I was aware that the Average Wholesale Prices, or ‘AWPs,’ published in the drug compendia, such as Red Book and Blue Book/First Databank, were list prices not reflective of the actual prices - net of discounts, rebates, and chargebacks - paid by pharmacies in the marketplace. In particular, I was aware that the differences between AWP published in the compendia and the actual prices paid in the marketplace were significantly greater for generic drugs. I was also aware that the difference between AWP published in the compendia and the actual prices paid in the marketplace could be substantial for intravenous solutions (such as sodium chloride and dextrose) and injectable drugs commonly infused or injected into patients. Based on my discussions with them, I understand that these facts were well known among the IDPA staff who worked with Illinois Medicaid’s pharmacy benefit.”
- “Finally, as noted, it was also well understood by pharmacists and Medicaid officials with whom I spoke that the difference between AWP published in the compendia and the actual prices paid in the marketplace could be substantial for intravenous solutions and other injectable and infusion drugs commonly used by IV pharmacies. Based on my previous work in a hospital pharmacy, I was aware that published AWP for these types of drugs could be several times greater than actual prices paid in the marketplace.”

(Affidavit of Ron Gottrich, ¶¶ 3, 8, Ex. 17.)

(m) Carl Shirley, Pharmacy Operations Manager in Indiana, testified:

Q. Thank you. I’m going to ask you about the state MAC program a little later, but can I ask you now, why did Indiana switch from an AWP minus 10 EAC for all legend drugs to a bifurcated AWP

minus 13 for brand-name drugs and AWP minus 20 for generic drugs?

A. I believe at the time the perception was that generic drugs, AWP information was not as accurate for generic drugs as it was for brand-name drugs, that is there was a greater spread on generic drugs. And if I also remember, it seems like there was some input from other states that using AWP on generic drugs, you should have a higher percentage off of your AWP for your EAC.

Q. When you say generic drug -- I'm sorry, strike that. You had stated that AWP information was not as accurate, though you didn't specify by what reference you were measuring its accuracy. Can you just tell me a little bit about what you were --

A. I think there was a general perception that the AWP for generic drugs were inflated. Seems like there was also some information from OIG or GAO or both or CMS or all three that questioned the use of AWP on generics. And, again, I'm going strictly by memory on this. It seems like that was part of the thrust behind the bifurcation of the reimbursement methodology for the two different types of legend drugs.

(12/2/08 Shirley Dep. 236:18-238:5, Ex. 18.)

(n) Brendan Joyce, Administrator of Pharmacy Services in North Dakota,

testified:

Q. But there were certain times where the department set MAC prices itself and other times where it used a vendor?

A. The MAC program started with just the department setting prices ourselves.

Q. Okay.

A. And then we completed the RFP and had a vendor come in to augment it, make it easier.

Q. Okay. And how did the department set MAC prices when the department was in charge of setting those prices?

A. Called pharmacies and asked them what their prices, actual acquisition costs were. And then chose a price to allow comparable reimbursement to brands where AWP were not inflated.

Q. What brand drugs would that be?

A. Most brand drugs AWP's were appropriate. The MACs are typically for generics.

Q. Okay.

A. And the generic AWP's were inflated and not rational or relative to any actual acquisition cost. So we contacted the pharmacies to determine what the actual acquisition cost was for the product. For instance, Prozac, when Prozac came on the market generically.

Q. Um-hum.

A. The AWP for the product was still at \$4, or something along those lines. Whereas, the actual cost to the pharmacy was 20 cents. We found that out from the pharmacies and set the reimbursement to where they would make the same gross margin on a generic product as they do on the brand products.

(12/12/08 Joyce Dep. 97:16-99:5, Ex. 19.)

\* \* \*

(o) Kevin Gorospe, Chief of MediCal Pharmacy Policy, testified:

Q. Good point. The AWP, at least to that second product, would be somewhere in the \$17 range, and if we looked at this first product listed, the one from Goldline, if you back out the dispensing fee, that figure drops to \$5.37?

A. That's correct.

Q. So the AWP would be somewhere between -- somewhere around \$6 roughly, maybe a little less?

A. Yes, that's correct.

Q. I wasn't a math major. So you would have one product with an AWP of around \$17, one generic product, and a therapeutically equivalent product with an AWP of roughly one-third of that.

A. That is accurate.

Q. And again, anyone in DHS who you know was pouring through or reading this report, would be able to -- would have learned that there were these wide variations in AWP's for generic products --

MR. GOBENA: Object to –

BY MR. COLE:

Q. -- correct?

MR. GOBENA: Sorry. Objection.

THE WITNESS: That is correct.

(3/19/08 Gorospe Dep. at 223:10-224:12, Ex. 20.)

\* \* \*

Q. Okay. Fair enough. If you were looking at spread as simply the difference between AWP and acquisition cost, would you -- has it been your experience, in your 25 years as a pharmacist, that the spread for generic drugs is greater than the spread for brand drugs?

MR. GOBENA: Objection. Form.

THE WITNESS: Yes.

(*Id.* at 240:1-8.)

Q. And then the first sentence of the following paragraph states “A rate of AWP minus 20 percent is still significantly higher than the pharmacy acquisition cost of generic drugs.” Did I read that correctly?

A. Yes.

Q. Is that consistent with your understanding at the time?

A. Yes.

Q. Did you have that understanding also going back to the late nineties, that AWP minus 20 percent is significantly higher than pharmacy acquisition costs for generic drugs?

A. Yes.

Q. Last sentence of that paragraph or that page, I guess, going over to the next page, “The reimbursement of generic drugs will still be significantly above pharmacy’s acquisition costs.” And then it goes on. Did I read that correctly?

A. Yes.

Q. Do you understand that to -- Withdrawn. So was it your understanding to the extent you recall this proposal that the reimbursement rate of AWP minus 20 percent was made knowing that reimbursement on that basis would be significantly higher than acquisition costs for generic drugs?

A. Yes.

(9/22/08 Gorospe Dep. at 593:20-595:5, Ex. 21.)

(p) Delaware received many HHS-OIG reports detailing how Medicare allowances for albuterol and ipratropium greatly exceed providers' costs for those drugs.

(12/9/08 Denmark Dep at 204:20-205:9; 208:11-20; 211:14-212:6, Ex. 22.) Delaware's response to a September 1996 OIG report stated as follows:

It is well known that [FUL] drugs usually have an AWP that is not related to any true cost. It is dramatically inflated and will influence any study that has to take it into account. Problems associated with MAC drugs will be addressed in any update to ingredient cost for the Delaware program. We would consider setting up a Delaware MAC for some drugs because we have no generic substitution now in Delaware.

Although prescription medications are an optional benefit under Medical Assistance, pharmacy services have played a major role in the treatment of recipients in the program. As you noted the ingredient price is only one portion of pharmacy cost. The ingredient cost is becoming less and less of a factor. Our program as well as the other states will have to address the other issues that you mentioned; [*sic*] particularly the requirement to provide professional services and pay transaction fees.

(Ex. 23 (Dey Ex. 612).)

(q) Jerry Dubberly, formerly the Pharmacy Director of Georgia Medicaid and currently the Chief of the Division of Medical Assistance, testified:

Q. I believe you testified a few minutes ago in response to some questions from Mr. Robben that you understood dating back to the early to mid-'90s that AWP was not an accurate reflection of what physicians or providers paid to acquire drugs.

Do you remember that question and answer?

A. Yes.

MR. SULLIVAN: Object to the form.

A. Yes, I do.

Q. (By Mr. Cole) And would you have acquired that knowledge then while you were working for the Erlanger Medical Center in Chattanooga as a staff pharmacist?

MR. SULLIVAN: Object to form.

A. Actually, as -- while I was working as the director of pharmacy that they outsourced me to -- while I was working for Erlanger, yes.

Q. So sometime in the 1990 to '96 time frame, then.

A. Correct.

(12/15/08 Dubberly Dep. at 299:2-22, Ex. 24.)

Q. (By Mr. Robben) Mr. Dubberly, have you ever heard of AWP referred to as "ain't what's paid"?

A. Yes.

Q. Is that a fairly common phrase?

A. Yes, it is.

Q. Common in the Medicaid director circles?

A. In Medicaid as well as other pharmacy circles.

Q. Are you a pharmacist?

A. I am.

Q. Is that something that you've heard throughout your pharmacy career?

A. Yes.

Q. Is that something that's been well known to Georgia Medicaid?

A. Yes.

MR. LAVINE: Object to form.

Q. (By Mr. Robben) For how long has that been well known to Georgia Medicaid?

MR. LAVINE: Object to form.

MR. SULLIVAN: Object to form.

A. I don't know when the department first had knowledge of that as an entity, but it has been common knowledge in the industry for quite some time.

Q. (By Mr. Robben) Has it been common knowledge at least since the 1980s?

MR. LAVINE: Object to form.

A. Are you asking about with the department or –

Q. (By Mr. Robben) Well, you said that you couldn't speak specifically to the department, but it's been common knowledge for some time. So I'm just trying to get a quantification of -- of that, "some time."

A. It's –

MR. LAVINE: Object to form.

A. It's been common knowledge to me since the mid-'90s.

Q. (By Mr. Robben) Excuse me?

A. Early to mid-'90s.

(*Id.* at 284:15-286:13.) Also, Dubberly agreed with Leo Sullivan's characterization of AWP as an unreliable acquisition price:

Q. (By Mr. Robben) Do you agree with Mr. Sullivan's characterization of AWP?

MR. LAVINE: Object to form.

A. I do.

\* \* \*

Q. Do you agree with Mr. Sullivan's testimony that just as everyone knows the sky is blue, your peers in state Medicaid

programs know that AWP is not a reliable source for the prices that physicians and pharmacies pay for drugs?

MR. LAVINE: Object to form.

MR. SULLIVAN: Object to form and asked and answered.

Q. (By Mr. Robben) You can answer.

A. I certainly hope so.

Q. What do you mean?

A. I can't imagine a person performing the job without that knowledge.

Q. Without the knowledge that AWP is not a reliable predictor?

A. Exactly.

MR. LAVINE: Object to form.

Q. (By Mr. Robben) So is it -- is it your testimony that a -- that a person couldn't hold a job as a -- as a pharmacy director or a Medicaid director in the United States and perform that job reliably and effectively if they didn't know that AWP wasn't a reliable predictor of acquisition costs?

MR. LAVINE: Object to form.

A. I think that's a personal judgment on -- on my part. I would -- I would question someone who did not have that knowledge.

Q. (By Mr. Robben) So you would question their -- their abilities and their -- their skills if they didn't know that AWP wasn't a reliable predictor --

A. Yeah.

Q. -- of acquisition cost?

MR. LAVINE: Object to form.

A. Yes.

(*Id.* at 290:11-292:18.)

Q. Is it feasible to just set reimbursement for all NDCs at AWP minus 65 percent?

A. No. The MAC rate typically applies to generics, and generics are typically based upon pricing studies that some of the government entities have done. There's a wider margin between the published AWP and the actual acquisition cost for those drugs.

(*Id.* at 76:1-9.)

(r) M. J. Terrebonne, Louisiana Pharmacy Director, testified that she has long been familiar with the "running joke" that AWP means "Ain't What's Paid":

Q. [The Baron's Hooked on Drugs article] also recorded the industry insiders joke that "AWP really means 'ain't what's paid.'" Do you see that?

A. Yes.

Q. Have you heard that?

A. Yes.

Q. You have heard that joke regarding AWP before. Have you heard it?

A. "Ain't what's paid"?

Q. Yes.

A. Yes.

Q. When is the first time you heard that?

A. I don't remember.

Q. It's been so long ago you can't even remember?

MR. FAUCI: Object to the form.

THE WITNESS: Yes.

\* \* \*

Q. As far as you can recall, you have always been aware of the joke "AWP equals ain't what's paid"?

MR. FAUCI: Object to the form.

THE WITNESS: Pretty much, yes. It's a running joke.

(3/31/08 Terrebonne Dep. at 184:9-185:14, Ex. 25.) Terrebonne testified that AWP and actual acquisition cost had two different definitions, and that AWP did not include rebates, chargebacks, and discounts:

Q. . . . Stated another way, did you expect that the AWP's reported in the compendia for generic drugs would actually represent the actual acquisition cost of pharmacies net of discounts, rebates and chargebacks? ... From 1991 through 2001.

A. Did I expect it? No.

Q. Why not?

A. Because I think both of those have two different definitions. AWP has a different definition than actual acquisition cost, and we were getting AWP's from First DataBank, not actual acquisition cost.

\* \* \*

Q. But you didn't think that the prices reported in the compendia were the actual average, net of all rebates, charge-backs and discounts, that pharmacies were actually paying from 1991 until 2001, did you?

A. That's correct, I did not.

(3/31/08 Terrebonne Dep. at 117:2-118:10, Ex. 25.) From reports issued by Myers & Stauffer for Louisiana, Terrebonne testified that Louisiana Medicaid understood that spreads between actual acquisition cost and AWP in excess of 100% frequently existed. (11/7/2008 Terrebonne Dep. at 66:11-67:11, Ex. 26.)

(s) Frank Tetkoski, Manager of the Maryland Pharmacy Services Department, testified:

Q. It could be even -- what was your understanding as to generic drugs between the relationship between AWP and WAC?

A. That the AWP for generic drugs could be off more than it is for brand names.

(12/11/08 Tetkoski Dep. at 159:15-19, Ex. 27.)

(t) Gary Cheloha, Pharmacist Consultant in Nebraska, testified:

Q. Okay. And then the cover of the letter, on the first page, it states that the Nebraska Department of Social Services (state agency) was 1 of 11 states randomly selected as part of a nationwide review. Nebraska reported drug expenditures of 60.3 million in calendar year 1994. Through statistical sampling, we obtained pricing information from 43 Nebraska pharmacies. We obtained 2,742 invoice prices for brand name drugs and 1,114 invoice prices for generic drugs. The overall estimate of the extent that AWP exceeded pharmacy purchase invoice prices was 18.7 percent for brand name drugs and 44.9 percent for generic drugs. The national estimates are 18.3 percent and 42.5 percent, respectively. So this report indicates that there's a much higher discount off of AWP for generic drugs than brand name drugs; is that correct?

MR. DUNNING: I'm going to object to form, foundation. The document speaks for itself.

THE WITNESS: Repeat the question. I'm not sure that—relatively, what this says, the discount was different for brand than—or the difference was different for brand than it was for the generic price.

Q. (BY MS. LORENZO) Right. And for generic drugs, the overall estimate was that AWP exceeded purchase price invoices was (sic) 44.9 percent?

A. That's correct.

Q. And it was 18.7 percent for brand name drugs; correct?

A. That's correct.

Q. If you'd turn to the second page of the cover letter, it states: In response to a draft report, the director of the state agency stated that our review was the first information of its type that the state agency has had access to in ten years. The director also stated that the information would be useful to the state agency in setting adequate pharmacy reimbursement rates in the future. The complete text of the director's comments are included in Appendix 4.

So would you agree that, as represented here, Nebraska Medicaid had an opportunity to review the draft report?

A. Yes.

(12/2/2008 Cheloha Dep. at 224:12-226:17, Ex. 28; Ex. 29, Dey Ex. 921)

Q. . . . So at the time that Nebraska received this report, which showed discounts off of AWP ranging for brand drugs at 18.7 percent and for generic drugs at 44.9 percent, what was Nebraska's EAC?

A. EAC was AWP minus 8.71 percent for direct.

Q. Okay. And I think that you've testified previously that, several years later, that was recalculated to be an EAC—AWP minus 10 percent, and that was cost neutral?

A. That's correct.

(*Id.* at 235:21-236:10, Ex. 28.)

(u) Ed Vaccaro, Chief Pharmaceutical Services Consultant and Assistant Director of Office of Utilization Management, testified that the state of New Jersey was “aware of a significant difference between possible acquisition costs and AWP” for drugs in this case:

Q. Now, did New Jersey know that the spreads that are claimed in those Complaints that Abbott and Dey and Roxane may have had were as much as a thousand percent?

A. For certain products we were aware of a significant difference between possible acquisition costs and AWP.

(12/2/08 Vaccaro Dep. at 170:10-17, Ex. 30.)

\* \* \*

Q. And then the last sentence [of a 1996 OIG report] says, “The estimates exclude the results obtained from non traditional pharmacies, nursing home pharmacies, hospital pharmacies, home IV, et cetera because such pharmacies purchase drugs at substantially greater discounts than retail pharmacies and including them would have inappropriately inflated our percentages.”

Did you know, prior to New Jersey receiving this report, that the non traditional pharmacies purchased drugs at a greater discount than your traditional retail pharmacies.

A. Yes.

A: The state was aware of that.

Q. And do you know how substantial the difference was?

A. It's substantial.

(*Id.* at 653:16-654:13.)

(v) Myers & Stauffer prepared numerous reports to state Medicaid programs throughout the relevant time period evaluating the extent to which acquisition costs differed from AWP's reported in the compendia. Its 30(b)(6) witness, T. Allen Hansen, testified that Myers & Stauffer "made observations in [its] reports on more than one occasion contrasting a relatively a relatively tight distribution of the data – and this is talking about actual acquisition cost as a percent of AWP – a relatively tight distribution of the data points for single source drugs and a comparatively more diffuse, more variable distribution for multisource drug products."

(12/10/08 Hansen Dep. at 209:21-210:10, Ex. 216.)

2. Numerous federal officials provided testimony regarding whether they believed AWP's reported in the compendia provided a reliable source of market prices for generic drugs:

(a) Larry Reed has been employed by HCFA since 1978. (9/26/2007 Reed Dep. at 41:14-43:17, Ex. 31.) Since that time, he has held a number of positions, including Branch Chief of the Medicaid Non-Institutional Payment Policy Branch and Technical Director for the HCFA Medicaid Program. (*Id.* at 55:13-62:14.) His current position is Technical Director of the CMS Medicaid Division of Pharmacy. Mr. Reed testified:

Q. Did you have discussions about the significantly greater difference between AWP and acquisition costs for generic drugs as opposed to branded drugs?

MS. MARTINEZ: Objection, form.

MS. POLLACK: Objection, form.

THE WITNESS: I believe we had those discussions.

BY MR. TORBORG:

Q. Who were those discussions with?

MS. MARTINEZ: Objection, privilege.

MR. TORBORG: We have to decide who the discussions were with before we can decide what privilege applies.

MS. MARTINEZ: No, the discussions were within HCFA, and if they related to an anticipated decision by HCFA, then it would be privileged and then you would be instructed not to answer. If you had a discussion with somebody in the outside that's not related to a policy decision like that, you can—you can answer.

THE WITNESS: I can't answer.

BY MR. TORBORG:

Q. So you had discussions within HCFA about the significantly greater difference between acquisition costs and AWP for generic drugs as compared to branded drugs, correct?

MS. MARTINEZ: Objection, form.

THE WITNESS: We did have those discussions.

BY MR. TORBORG:

Q. And I'm not permitted to probe your memory here today because you've been instructed not to answer, correct?

A. Correct.

(9/27/07 Reed Dep. at 519:9-520:22, Ex. 32.)

\* \* \*

Q. I'm trying to . . . figure out what decision or policy those discussions related to.

A. The decision would be how to look at this and reviewing a state plan.

Q. And whether or not to approve or disapprove the plan?

A. That could be part of that decision.

Q. Which would ultimately determine how much providers were paid for drugs, correct?

A. Correct.

(*Id.* at 523:3-13.)

(b) Charles Booth, Former Director of Office of Payment Policy, testified:

Q. During this time period from 1991 to 1997 what was your understanding of what AWP referred to?

A. AWP was what the manufacturers chose to put in the compendia.

Q. At any time in this time period did you understand AWP to refer to a calculated average of wholesale prices that were charged to physicians or other purchasers of these products?

A. No.

MR. GOBENA: Object to the form.

Q. At any time were you ever fooled into believing that average wholesale price somehow was the same thing as acquisition cost?

MR. GOBENA: Objection to the form.

MR. WINGET-HERNANDEZ: Objection.

A. Was that a leading question?

Q. Yes, sir.

A. Fine. I did not believe that there was a relationship to any great extent between acquisition costs and AWP.”

(10/29/07 Booth Dep. at 518:10-519:8, Ex. 33.)

\* \* \*

Q. And so certainly nobody expressed to you an expectation that there would be some relationship between acquisition cost and AWP?

MR. GOBENA: Objection, form.

A. I certainly don't remember any.

Q. Did that change over time?

A. No.

(*Id.* at 310:9-15.)

\* \* \*

Q. Was it the position within payment policy that AWP was inflated and overstated the price that providers actually paid for drugs?

MR. BREEN: Objection to form.

MR. GOBENA: Join.

A. Yes, by some percentage, and it of course varied by drug . . . .

(*Id.* at 236:17-237:1.)

(c) Sue Gaston, Former CMS Health Insurance Specialist, testified:

Q. And did you understand that the average wholesale price for multiple source drugs in particular was not a reliable indicator of the cost at which pharmacies and physicians purchased drugs?

MS. MARTINEZ: Objection to form.

MS. ALBEE: Objection to the form.

MR. WINGET-HERNANDEZ: Objection, form.

A. As I stated before, my understanding is that I looked at average wholesale price, direct price, wholesale acquisition costs, the prices that were available in the compendia, and generally speaking the average wholesale price was a higher price at that point others.

(1/24/08 Gaston Dep. at 218:2-14, Ex. 34.)

(d) Robert Vito, Regional Inspector General, testified:

Q. For many drugs, especially the growing number coming off patent and going generic, the drug providers actually pay wholesale prices that are 60 to 90 percent below the so-called average wholesale price, or AWP, used in reimbursement claims. When did you become aware of the fact that there were—that generic drugs were being sold to providers at amounts 60 to 90 percent below average wholesale prices?

MR. NEAL: I'll object to the form of the question.

THE WITNESS: I think we became—I mean, of course, this article pointed it out, but I think we also, our work in albuterol sulfate, which is the generic, demonstrated some of those issues as well, as well as some of the other work that we have done here. I believe at this time Leucovorin was also a generic, so there were other generic products that we had seen and seen some pricing variations on.

BY MR. TORBORG:

Q. Do you recall discussions with CMS officials in this time frame about the fact that generic drugs were selling at amounts 60 to 90 percent below the so-called average wholesale prices?

MR. NEAL: Objection as to form.

THE WITNESS: I believe when we issued our reports, the reports pointed out that the products were selling below the—the AWP and that clearly some of the products were generic.

(6/20/07 Vito Dep. at 490:9-491:18, Ex. 35.)

(e) Kathleen Buto, former Director of CMS's Bureau of Policy Development, testified:

Q. That's right. Now, there's no doubt that as of 1991 HCFA knew that unmodified AWP, a hundred percent AWP, did not represent actual acquisition cost, right?

A. Yes.

Q. And there was no doubt that in 1991 HCFA knew that there was no predictable relationship between AWP and actual acquisition cost, right?

A. Based on the surveys from the IG, that's correct. That was our belief. Again, we didn't have independent data.

Q. Right. That was your belief at that time, right?

A. That's correct.

(9/13/07 Buto Dep. at 433:04-18, Ex. 36.)

(f) Ben Jackson, Acting Director, Operational and Program Reviews, Health Care Financing Audit Division, Office of Inspector General, testified:

Q. Even though you were one of the leading people at OIG during the 1990s in this area no one even asked you whether you thought this lawsuit had any merit, right?

MR. AZORSKY: Objection, form.

A. No. But they wouldn't.

Q. Why wouldn't they want to hear what people who were there thought before they filed a lawsuit?

A. That's a good question. I mean, I think our reports kind of speak for themselves. I mean, the thoughts are in the reports, the writing of the reports. So, I mean, it's there. It is what it is.

Q. What do you mean by that?

A. Well, it's documented in these reports. I mean, we've got, what, eleven state reports in one batch and we've got eight in the next. We've got four roll-up reports and we've got follow-up reports to those. So, I mean, it's pretty well documented what the findings were, right? So --

Q. And the findings are that states are paying more than acquisition cost, particularly for generic drugs, right?

MR. AZORSKY: Objection to form.

MR. DRAYCOTT: Objection.

A. Yes.

(12/12/08 Jackson Dep. at 394:6-395:10, Ex. 37.)

(g) CMS's Deidre Duzor, currently the Director of the Pharmacy Division for Medicaid, testified that she understood that "the reported prices for drugs generally [are] not reliable." (10/30/07 Duzor Dep. at 111:19-12:4, Ex. 38.)

(h) Former CMS Administrator, Bruce Vladeck, testified:

A. Well, I actually -- in the 1980s, I believe, when I was first becoming involved in some of these issues in health care

economics was the first development of hospital group purchasing operations, and I recall -- and the first widespread circulation of the -- of "Modern Healthcare," the magazine, and I recall monthly headlines in "Modern Healthcare" about group purchasing operations being -- achieving discounts of 98 and 99 percent in their purchase of basic infusion products and sterile supplies. So, my perception was that on the supply market, which, again, I understood and still would contend is actually a separate market from the pharmaceutical market that list prices, are essentially entirely meaningless and that only the weakest and smallest scale buyers pay anything close to it.

Q. And so, as of 1993, for example, would you be surprised if a single bag of sodium saline solution sold to a provider who bought maybe five would pay \$10 per bag, and a large purchaser who bought a very large volume would pay less than a 10 dollar?

MS. BROOKER: Objection. Form.

A. I would not have been surprised.

(5/04/07 Vladeck Dep. at 145:9-146:12, Ex. 39.)

(i) Paul Chesser was the OIG agent who analyzed invoices pulled in conjunction with the 1994 AWP study. He testified that he found "significant discounts" on injectable solutions—at a "90 plus percent" discount from AWP. (10/28/08 Chesser Dep. at 626:6-630:12, Ex. 40.) Mr. Chesser testified:

Q. Would it surprise you to see discounts in the 90 percent plus range for these injectables?

A. No. It was very common.

(*Id.* at 630:5-7.) Other work papers obtained for this 1994 study showed acquisition prices for the four drugs at issue in this litigation – Vancomycin, sterile water, sodium chloride, and dextrose solutions. (Ex. 41.)

3. Numerous federal government reports and other documents acknowledge larger percentage spreads for generic drugs.

(a) On September 18, 1986, the HCFA Regional Administrator for Region VI sent the Director of Bureau of Eligibility, Reimbursement and Coverage comments regarding a proposed rule on limits on payments for drugs. (Ex. 42 (Abbott Ex. 1109).) The memorandum included the following statement:

The mandatory discount of 25 percent off the retail price of brand name drugs for reimbursement of multisource drugs is insufficient. Data exist which reveal that generic drugs are marked up anywhere from 25 to 150 percent.

(*Id.*)

(b) In August of 1989, The United States Senate Special Committee on Aging issued a Majority Staff Report titled, "Prescription Drug Prices: Are We Getting Our Money's Worth?" in August 1989. (Ex. 43 (Abbott Ex. 81).) This Report described "two markets" in the United States for prescription drug sales: "[A] price competitive market, characterized by deep discounts off the published list price, and a high priced market, where retail customers, Medicare and Medicaid purchased their prescription drugs." The Report further stated that the Department of Veterans Affairs received average discounts of 67% off of AWP for generic drugs, and that "Hospitals, Health Maintenance Organizations, and nursing homes that contract with wholesalers to purchase prescription drugs from a predetermined list are able to achieve discounts of up to 99% off the manufacturer's published "Average Wholesale Price" (AWP), even for brand name products." (*Id.* at 11.)

(c) In September of 1989, OIG issued a Management Advisory Report, titled "The Use of Average Wholesale Prices in Reimbursing Pharmacies Participating in the Medicaid and Medicare Catastrophic Coverage Act Prescription Drug Program." (Ex. 44 (Dey Ex. 46).) That report stated that "generic drugs can be purchased at a greater discount than Brand name

drugs – the discounted AWP had less impact on generic drugs.” (*Id.* at 6.) The OIG also noted that “AWP is not a meaningful figure.” (*Id.* at 1.)

(d) In 1991, HCFA acknowledged in the Federal Register that “many drugs could be purchased for considerably less than 85 percent of AWP—particularly multiple-source.” (Ex. 45 (59 Fed. Reg. 59524).)

(e) In October 1992, the OIG published a report titled “Cost of Dialysis-Related Drugs.” (Ex. 46 (Abbott Ex. 82).) As part of its study, OIG pulled pharmacy invoices for drugs, including Abbott’s vancomycin, to determine the “estimated acquisition cost” for each product. (*Id.*) OIG compared its estimated acquisition cost for vancomycin to the median published AWP for four different manufacturers of vancomycin. (Ex. BT; Ex. BS at 6 (Abbott Ex. 82).) OIG determined that the estimated acquisition cost of 500 ML of vancomycin was \$5.00, while the median published AWP was \$19.17. (*Id.* at 1, 2, 6.)

(f) In November 1992, the OIG issued a report titled “Physicians’ Cost for Chemotherapy Drugs.” (Ex. 47 (Abbott Ex. 79).) Appendix III to the report showed the “invoice costs” for various chemotherapy drugs, “expressed as a percentage below the AWP.” Appendix III showed much higher discounts for generic drugs. (*Id.* at Appx. III.) The report also stated: “Our results indicate that, for the physicians surveyed, the 13 chemotherapy drugs can be purchased at amounts below the established average wholesale price (AWP) and that AWP is not a reliable indicator of the cost of a drug to physicians.”

(g) In March 1993, the United States General Accounting Office prepared a Fact Sheet for Congressional Committees titled “Outpatient Drug Costs and Reimbursements for Selected Pharmacies in Illinois and Maryland.” (Ex. 48 (Abbott Ex. 458).) GAO compared Illinois and Maryland Medicaid drug payments to acquisition cost, revealing numerous instances

where AWP's were several times higher than the prices paid for generics by hospital and nursing home pharmacies. (*Id.* at Appendices II & III.)

(h) On June 10, 1996, Barron's published an article titled "Hooked on Drugs." (Ex. 49 (Abbott Ex. 16).) Among other things, the article stated:

This sampling showed that for single-source drugs still enjoying patent protection . . . , true wholesale prices are generally 10%-20% below published AWP's. But for generic drugs, nearly every manufacturer's price was 60%-85% below the published average wholesale price.

The pricing unreality is even worse for intravenous nutritional and solutions, a category dominated by Abbott Laboratories and Baxter International. Catalog wholesale prices for these items are, on average, 80%-98% below those companies' AWP's.

(i) In 1996 and 1997, OIG reported average spreads for generic drugs that were more than three times greater than those for branded drugs (74% versus 20%, respectively). (Ex. 50 (Abbott Ex. 158).) OIG's work found spreads well over 500% on many particular drug products, including on certain products at issue in these cases. (*Id.*) Many of OIG's reports stated: "The difference between AWP and pharmacy acquisition cost is significantly greater for generic drugs than brand name drugs." (Ex. 51 (Abbott Ex. 84).)

(j) In a 1997 and 1998, OIG reported spreads on most generics that exceeded 150%, with some as high as 1500%. (Ex. 52 (Abbott Ex. 49); Ex. 53 (Abbott Ex. 101).) Spreads for albuterol sulfate were 177%, and Vancomycin, 150%. (Ex. 52 (Abbott Ex. 49).) Spreads for albuterol sulfate were 292%, and ipratropium bromide, 155%. (Ex. 53 (Abbott Ex. 101).)

4. CMS's Deirdre Duzor testified that manufacturers reports AMPs to CMS electronically every quarter, which "[g]enerally, people in Medicaid dealing with drugs have access to." (3/26/08 Duzor Dep. at 672:7-12, Ex. 54.) CMS uses AMP information to compute

the “unit rebate amount” or URA, which “is the rebate that would be due on each unit of a drug. (*Id.* at 673:11-15.) And it’s provided to the states so that they can multiply the number of units they paid for times this figure in order to invoice the drug manufacturers for the rebates.” (*Id.* at 673:18-674:1.) States have received URA since 1990 for all the drugs it reimburses for by NDC number. Duzor testified that AMPs are “very transparent” for generic drugs because they can be computed by calculating 11 percent, prior to the early 1990s it was ten percent:

Q. Okay. So if you had the URA and you divided by .11, that would tell you what the AMP is, right?

\* \* \*

THE WITNESS: Yes. The AMPs have been fairly transparent for generic drugs.

\* \* \*

Q. But still, as a rule of thumb, you could get a pretty good idea of the AMP from just moving the decimal point over one spot on the URA for generic drugs, correct?

A. Right, for states it’s -- the AMPs for generics are very transparent.

Q. So since 1990, states have had access to the AMP information on generic drugs on a quarterly basis for each NDC that they reimburse on, correct?

\* \* \*

THE WITNESS: It was available to them, yes.

\* \* \*

Q. And they could have looked at that information, right?

\* \* \*

THE WITNESS: They could have.

\* \* \*

Q. For all you know, they may have, correct?

\* \* \*

THE WITNESS: They may have, yes.

\* \* \*

Q. Well, it's -- fair enough. You don't know what they actually did, but you do know they had the data that would have allowed them to do that?

A. Right. Yes, I do.

(*Id.* at 670-73, 679-82.)

5. Until calendar year 1994, Unit Rebate Amounts for the Medicaid Drug Rebate Program were 10 percent of the AMP for multiple-source drugs. In calendar year 1994, URA became 11 percent of the AMP for multiple-source drugs. CMS's Larry Reed testified that by knowing the URAs, state Medicaid officials could perform the "simple calculation to get back to AMP." (10/2/08 Reed Dep. at 1316:11-18; 1323:10-1324:8, Ex. 55.) Reed had access to AMP information, as did all of the analysts that worked on Medicaid rebates, most of which are people who evaluated state plans (*Id.* at 1094:20-1095:10.) Mr. Reed testified that the Medicaid statute did not prohibit HCFA from using AMP to approve or disapprove state plans. (9/26/07 Reed Dep. at 305:9-21, Ex. 31.)

6. Mr. Reed agreed that the federal statute discussing AMPs did not prohibit the Secretary from providing AMP information to the states. (10/02/08 Reed Dep. at 1311:5-9, Ex. 55.) Similarly, Mr. Reed is not aware of any place in the rebate agreement, statute or other place in the federal regulations that provides the Secretary cannot share AMP information with the states. (*Id.* at 1311:11-1312:4.)

7. Mr. Reed testified that "HCFA's regulation of manufacturers was limited to the rebate program" and "[t]here was no regulation on the payment side that was directed directly to

manufacturers.” (9/27/07 Reed Dep. at 362:10-13, Ex. 32.) Mr. Reed testified that HCFA never issued guidance to manufacturers regarding AWP:

A. I think we did talk about that earlier today. Our expectation would be that that -- that would -- that is a price that we would use ourselves for the federal upper limits, and it would be used in approval -- in actions on state plan amendments.

Q. But it wasn't an expectation that was based on any discussions that you had with Abbott, was it?

MR. HERNANDEZ: Objection, form.

MS. MARTINEZ: Objection, form.

THE WITNESS: There was no -- there was no policy guidance, no regulation to any manufacturer on the definition of AWP for the Medicaid program.

(*Id.* at 589:6-20.)

8. Ms. Duzor also testified that certain states, like Texas, actually request AMPs from manufacturers and that any state would be free to do so and consider AMPs in setting their reimbursement rates:

Q. So any state would be free to request AMP information from manufacturers?

A. Any state would be free to. They can't -- there's no federal requirement, so they really can't penalize manufacturers or not make their drugs available to their beneficiaries for failure of them to give them the AMPs.

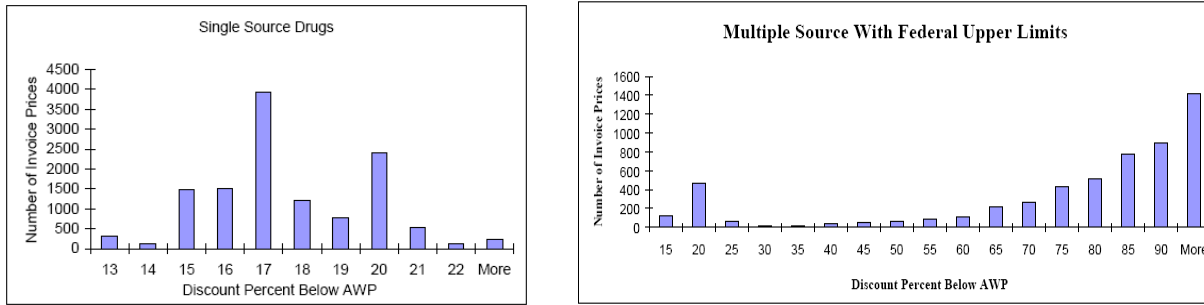
Q. And to the extent states do correspond with manufacturers and obtain pricing information or information about AMPs, WACs and things of that nature, is that information that the states could legitimately consider in the course of determining what their reimbursement rates are?

\* \* \*

THE WITNESS: Yes, I think they can.

(3/26/08 Duzor Dep. at 772-74, Ex. 54.)

9. In September of 2002, OIG prepared a report titled “Medicaid Pharmacy – Additional Analysis of the Actual Acquisition Cost of Prescription Drug Product” which contained the following bar graphs depicting their findings regarding the discounts below AWP for single source drugs and multiple-source drugs with federal upper limits.



(Ex. 56 at 5, 9.)

10. Ven-A-Care’s Lois Cobo testified regarding an instance where his pharmacy, Cobo Pharmacy, purchased Abbott’s sodium chloride:

Q. And if you were paying in the order of magnitude of a dollar or two a bag when you were purchasing it in a case size, would you be surprised if calling Abbott to order a single bag might cost you \$10 or \$11 for that bag?

MR. BREEN: Objection, form.

A. Once again, it’s a hypothetical.

Q. Right. Because you never did that, right?

A. You want to know if I called Abbott and I said I need one bag –

Q. I’m Luis Cobo.

A. -- and they said, okay, we’re going to sell you one bag. And then they’re going to tell me what price?

Q. Right.

A. What price are they going to sell it to you?

Q. \$13.

A. \$13. For one bag?

Q. Right.

MR. BREEN: Objection, form.

A. And I don't have a contract?

Q. No, sir. You are a stranger to Abbott.

MS. BROOKER: Objection, form.

A. I guess it would surprise me.

Q. Because it's too low?

A. Oh, I don't know. I would have a -- under that scenario if I needed the product bad enough and I realized I didn't have a contract or a direct account or something and I had no other resource to purchase it and I've got somebody out to take care of then I would pay it. I don't know if it would be too low or not by their standards.

Q. You said --

A. I would hope this they would give it to me also.

Q. You said that it would surprise you if Abbott would be willing to sell it to you at \$13. Is that what would surprise you?

MR. BREEN: Objection, form.

A. Correct.

Q. You would expect them to charge even more for that sort of a small sale?

A. I wouldn't have any expectations under that scenario, because it -- I mean, you're asking me to comment on something, on a situation, that I don't envision in the real world. So --

Q. Well, it never happened for you because you were a large -- I mean, not a large. But you were a large purchaser relative to someone who might need just one or two bags, right?

MR. BREEN: Objection, form. This line of questions has been asked and answered and asked and answered. And how long are you going to go with it? The same question over and over again.

MR. COOK: Could you read back the last question, please?

(Whereupon, the requested portion was read by the reporter.)

MR. BREEN: Objection, form.

A. Rather than the hypothetical, let me just reflect on reality. Instead of the one or two bags, I had an incident in my practice many, many years ago, Cobo Pharmacy -- this is after Abbott had stopped having direct accounts with pharmacies. I don't know when that was, but that's how far back it goes. And I had a urologist that called me and needed some -- a bag of irrigation solution and couldn't get it at the hospital, couldn't get it anywhere. And he asked me to take care of it for him and I did. And I called Abbott and they told me, no, we can't sell you just one or two bags. You have to buy an entire case. And they sold me the entire case. But they sold me at some list price or whatever it was. They did not give me any kind of a discount or break or direct price or contract price or wholesale cost or anything like that. So that's the way that that transaction was handled and I would assume it would be the same. The problem I'm having trouble getting past is the one bag scenario. So I mean, I only have reality to reflect on.

(1/8/2008 Cobo Dep. at 132:13-136:8, Ex. 57.)

11. A 1998 report issued by the Congressional Budget Office, titled "How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry," contained the following statements:

- "Competition in the pharmaceutical market takes three forms: among brand-name drugs that are therapeutically similar, between brand-name drugs and generic substitutes, and among generic versions of the same drug. Manufacturers of brand-name drugs compete for market share primarily through advertising and the quality of their products (including efficacy and side effects), as well as through pricing. Manufacturers of generic drugs increase their market share mainly by lowering prices."
- "By making generic entry easier and less costly, the Hatch-Waxman Act helped increase the number of generic manufacturers producing the same drug. As the number of [generic] manufacturers rises, the average prescription price of a generic drug falls."
- "Other studies have also concluded that prices of generic drugs decline in response to increased generic competition. Economist Richard Caves and colleagues found that as the number of generic manufacturers increased from one

to 10, the average generic price fell from 60 percent to just 34 percent of the brand-name price. With 20 manufacturers, the generic price was only 20 percent of the brand-name price. Since generic prices tend to fall as the number of producers rises, generic manufacturers are most profitable when they are one of the first to enter a market.”

(Ex. 58 at xi, xiii, 32 (Abbott Ex. 474).)

12. On or around August 30, 2004, Abt Associates prepared a report for CMS titled “Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices.” (Ex. 59 (Abbott Ex. 381).) The report was co-authored by Stephen W. Schondelmeyer. The report contained the following statements regarding pharmaceutical pricing:

#### **Drug Product Type Variations**

The pricing patterns of brand name drug products and generic drug products can be quite different. For most brand name drug products that are still covered by patent or exclusivity terms, the price relationship between list prices (AWP and WAC) and actual transaction prices (actual acquisition cost or average selling price) for a given class of trade is reasonably predictable. That is, the WAC is equal to, or very close to (+ or - 5%) the actual acquisition cost for the community pharmacy class of trade and the AWP is typically 20 to 25 percent above the WAC or, alternatively, WAC is 16.67 or 20 percent below AWP. In such cases, a payment policy based on AWP (i.e., usually AWP minus a certain percent) may be relatively accurate.

\* \* \*

The relationship between list prices (AWP and WAC) is much less predictable for generic drugs than it is for brand name drugs. Some generic drug products will have AWP that are the typical 20 to 25 percent above the WAC, but it is not unusual to see generic drug products with an AWP that is 50 to 100 percent, or more, above the WAC. Even more volatile is the relationship between the list prices (AWP or WAC) and actual acquisition cost for generics. Generic firms often discount their actual net price to the pharmacy to compete with other generics, but they do not always reflect these discounts in lower AWP or WAC list prices. Generic prices are also relatively volatile, because the market for generic drugs is effectively a commodity market. Thus, AWP-based payment policy is much less accurate for these drugs than it is for the branded drugs. Medicaid drug payment policy reflects the lower

market prices for generic drugs by placing a FUL (a federal MAC or a state MAC) on many generic products.

(*Id.* at 17-18.)

13. The Abt report also contained the following definition of AWP:

***Average Wholesale Price (AWP).*** The Average Wholesale Price (AWP) is a list price used for invoices between drug wholesalers and pharmacies or other appropriate drug purchasers and is typically used as a benchmark for all classes of trade without adjustment for discounts, rebates, purchasing allowances, or other forms of economic consideration. The AWP is set directly, and published, by most drug manufacturers with an effective date and remains in effect until a change in price is published. Some drug manufacturers argue that they do not set the AWP, but instead either the wholesaler or the drug price databases set the AWP. Even when the AWP is actually calculated by a wholesaler or a drug price database, these sources typically calculate the AWP as a fixed percentage above the WAC (i.e., typically 20 or 25 percent above WAC for brand name drugs) so that, in effect, by setting the WAC the drug manufacturer also sets the AWP for a drug product. AWP has been a term that typically does not include adjustments for discounts, rebates, purchasing allowances, or other forms of economic consideration. The AWP is typically 20 to 25 percent above the WAC for brand name drugs, but may be considerably higher (20 to 70 percent) than WAC for generic drugs. Because of different levels of discounts across drug products and specific classes of trade, the AWP does not generally have a reliable relationship to the actual acquisition cost. Within the retail class of trade, AWP may have a consistent relationship with the actual acquisition cost for single source brand name (patented and exclusivity protected brands) drug products, but not for innovator multiple source (off-patent brands) or non-innovator multiple source (generic) drug products.

(*Id.* at 14-15.) Dr. Schondelmeyer repeated that definition of Average Wholesale Price on page 25 of the expert report that he served for the DOJ Actions.

## II. MEDICAID

### A. Federal Regulations

14. State Medicaid programs are required, by statute, to set Medicaid payment rates “sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.” 42 U.S.C. § 1396(a)(30)(a)(30)(A).

15. On July 31, 1987, the United States Department of Health and Human Services (“HHS”) published a final rule in the Federal Register titled, “Medicare and Medicaid Programs; Limits on Payments for Drugs.” (52 Fed. Reg. 28648 – 28658) (Ex. 60 (Abbott Ex. 284).) This rule set forth federal regulations, 42 C.F.R. §§ 447.301, 447.331, 447.332, 447.333, pertinent to federal government’s financial assistance to the state Medicaid programs relating to their payments for prescription drugs at all times relevant to the United States’ cases against Defendants (hereafter, the “DOJ Actions”). The regulations set forth at 42 C.F.R. §§ 447.301, 447.331, 447.332, 447.333 will be referred to herein as the “1987 Medicaid regulations.”

16. On September 1, 1987, CMS<sup>2</sup> Administrator William Roper, M.D. wrote to the President of the American Pharmaceutical Association (“APA”) regarding the 1987 Medicaid regulations. (Ex. 61 (Abbott Ex. 762).) Dr. Roper addressed the APA’s concerns that the “final Medicaid rule governing upper limits for prescription drugs does not assure adequate reimbursement to pharmacists.” Dr. Roper’s letter stated:

Please note that it was never our intent to set forth a particular payment system that must be followed by the individual State Medicaid agencies. Rather, it has always been our intent to permit and encourage the States to exercise maximum flexibility in designing a variety of payment systems that would be subject to

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<sup>2</sup> As used herein, the term CMS includes the Health Care Financing Administration (“HCFA”), as CMS was previously known.

maximum payment levels established by Federal regulations. Moreover, these maximum payment levels include sufficient margins in both the mark-up factor for generic substitutes and the reasonable dispensing fees that would enable pharmacists to realize profits through prudent purchasing and efficient business operations.

(*Id.*)

17. The APA also sent CMS a list of questions regarding the 1987 Medicaid regulations. (Ex. 62 (Abbott Ex. 763).) CMS prepared a response to these questions which stated:

Q. What will HCFA do if States with inadequate drug reimbursement make no changes subsequent to the effective date of the new HCFA regulation?

A. We do not anticipate such a situation occurring because the aggregate payment limit on HCFA listed drugs, as well as the general limit on sole source and non-listed multiple source drugs, affords State agencies wide latitude in developing their own payment schemes to suit local conditions and unusual circumstances that may arise from time to time. For example, State agencies may retain already existing so called "mini-MAC" programs, which they have established on specific drugs either equal to or at levels lower than those established under the Federal MAC limits. Additionally, many States' programs extend to drugs not now covered by the MAC limits. Moreover, under the aggregate limits, State agencies are free to experiment with alternative payment systems. For example, letting contracts on a competitive basis for pharmaceutical services with selected pharmacies to Which recipients may go for drugs without incurring a copayment, or systems identical or similar to PhIP or CIP. This policy will also allow States to alter payment rates for specific listed drugs without first having to obtain permission from HCFA. States then will be able to respond rapidly to sudden price fluctuations which may threaten the supply of specific drugs on the HCFA list without having to pursue a cumbersome approval process. A final advantage of the aggregate limit methodology is ease of administration at the Federal level and the lack of administrative burden on State programs.

(*Id.*)

18. CMS officials involved in administering the Medicaid drug benefit at the federal level testified that the 1987 Medicaid regulations provide states with maximum flexibility in designing their systems. For example:

(a) Larry Reed testified:

I think the states have a fair amount of flexibility under the regulation to look at a number of factors of what they were considering in determining their EAC.

(10/02/2008 Reed Dep. 1373:14-17, Ex. 55.)

(b) Dennis Smith became the Director of the Center for Medicaid and State Operations (a division of CMS) in July 2001. (2/26/2008 Smith Dep. at 17:16-18:4, Ex. 63.)

While he was at CMS, Smith was the most senior person at CMS with day-to-day responsibilities relating to Medicaid operations. (*Id.* at 39.) Mr. Smith testified:

A. There are a number of different variations. Again, states using AWP minus a percentage that's further modified by maximum allowable cost. That's further modified by a wholesale acquisition cost. So states have flexibility, all of which would be approvable, because again, Medicaid is designed to provide the states with flexibility. This is not a national you will pay all providers one way. There is flexibility for the states to choose among different ways. And states clearly do pay differently. But they are approvable.

(*Id.* at 139:16-140:6.)

(c) Thomas A. Scully was the Administrator of CMS from May 2001 through January 2004. (5/15/2007 Scully Dep. at 97:12-15, 50:8-13, Ex. 64.) Mr. Scully testified regarding the state Medicaid pharmacy programs:

A. Again, it depends on the states. Every -- there's no one Medicaid program. There's 50 different state Medicaid programs, and they're all different. Tempe looks nothing like California's Medicaid program, and North Dakota's looks nothing like Florida's, so making a statement like that is impossible.

(7/13/2007 Scully Dep. at 567:14-20, Ex. 65.)

(d) Nancy Ann Min DeParle was the HCFA Administrator from October 1997 through October 2000. (5/18/07 DeParle Dep. at 54:6, 55:20-56:1, Ex. 66.) Ms. DeParle testified:

Q. Why do you think -- if you think at all -- the states had different reimbursement methodologies?

A. Well, that was because the general rule on the Medicaid program was that if you've seen one state Medicaid program, you've seen one state Medicaid program. That there was very little in common among the programs. And what I recall knowing was that the federal law says if you have a program you have to have hospital coverage, but that that could vary from -- Virginia had two days of hospital coverage to New York where it was unlimited.

(12/5/2007 DeParle Dep. at 441:10-22, Ex. 67.)

19. Officials who administered Medicaid pharmacy programs at the state level testified regarding the flexibility afforded by federal law. For example:

(a) Cody Wiberg started with State of Minnesota Medicaid program in 1999 as Pharmacy Director and has served as the Executive Director of the Minnesota Board of Pharmacy since September 2005. (3/14/2008 Wiberg Dep. 23:12-24:15, Ex. 68.) Mr. Wiberg testified:

Q. Okay. I believe you also testified to a phrase that if you've seen one state Medicaid pharmacy program, you've only seen one. Would you agree that states have a flexibility in determining how they structure their -- their own program?

A. Yes, they do.

(*Id.* at 262:1-6; *see also id.* at 199:5-22.)

(b) Robert P. Reid served as the Administrator of the Ohio Medicaid Pharmacy Service Unit from 1991 to 2001. (12/15/2008 Reid Dep. at 61:10-21, Ex. 2.) Mr. Reid testified:

Q. Tell me about the e-mail connection that you had with the other states.

A. Yeah. Carolyn Sojourner, who was the pharmacy administrator for South Carolina, took it upon herself to create a National Association of Medicaid Pharmacy Administrators. That was that - - yeah, that was it. And every time anybody on the 50 states asked a question, all 50 states got to see the question. And any time that the states -- any of the states would reply to the question, if they had replied to all, then every state would be privy to the answers. Very informative. All 50 Medicaid agencies are different, of course. If you've seen one, you've seen one. But people are interested in what their peers are doing.

(*Id.* at 86:6-21.)

(c) David Campana has been responsible for the administration of Alaska Medicaid for eighteen years. (8/19/2008 Campana Dep. at 22:1-19, Ex. 8.) As Alaska's 30(b)(6) witness, he testified that the state had "substantial flexibility" and "increased freedom from Federal Rules" in establishing reimbursement rates, which he understood permitted states to "take account of local circumstances." (*Id.* at 156:18-158:6; 8/20/2008 Campana Dep. at 763:10-764:11, Ex. 9.)

(d) Carl Mark Shirley serves as Pharmacy Operations Manager in the Indiana Family and Social Services Administration ("Indiana Medicaid"). (12/2/2008 Shirley Dep. at 31:21, Ex. 18.) He has been in that position since November 1981. (*Id.* at 35:5-7.) Mr. Shirley testified that CMS expected States to look at both pieces of reimbursement [drug cost and dispensing fee] –

Q. Did Indiana Medicaid have an understanding as to whether dispensing fees needed to be separate and distinct from EAC determinations?

MR. JULIE: Objection to form.

A. HCFA and CMS seemed to be very focused on states that were doing anything with their pharmacy reimbursement in that if states

were going to do something with the EAC component, they needed also be cognizant of what the dispensing fee was.

(12/3/2008 Shirley Dep. 640:16-641:4, Ex. 69.)

Q. When Ms. St. Peter-Griffith asked you about the dispensing fee and the ingredient costs being kept separate and distinct, you said that CMS was cognizant of what the dispensing fee was if states changed the ingredient-cost formulation or wanted states to be cognizant?

A. Yeah, exactly.

Q. What did you mean by that?

A. I think CMS is of the position that if the state is going to adjust its reimbursement methodology, it needs to look at both sides of the equation, just so that there's -- so that they're aware of what the state is doing, because they have to make the final determination as to whether or not something's going to create an access problem. That's where they typically get involved.

Q. And on what do you base your belief that that was CMS' interest?

A. I've seen something, again, I can't cite any specific notice or publication or something, but I recall that CMS definitely expects states to look at both pieces of reimbursement whenever pharm -- whenever states do something to their methodology.

Q. And so it's your understanding that CMS wants to make sure that if the state reduces the ingredient costs, that it looks at whether or not the dispensing fee needs to be increased?

MS. ST. PETER-GRIFFITH: Object to the form. That's not what he testified to.

Q. Is that --

A. No, I think they want states to look at the whole thing. If the state's going to do something to affect reimbursement, they want the state to make sure that the EAC determination is reasonable and appropriate and that the dispensing fee is reasonable and appropriate. They grant states great leeway in deciding what that reasonable and appropriate is. They've never dictated exact figures to states. It's just up to states to look at the whole thing. That's my sense from, you know, just seeing what they've issued and hearing discussions with CMS officials.

(*Id.* at 641:17-643:17.)

(e) James Kevin Gorospe serves as the Senior Pharmaceutical Consultant for California Department of Health Services. (3/19/2008 Gorospe Dep. at 68:8-69:21, Ex. 20.) Mr. Gorospe testified that the state Medicaid program had flexibility in proposing an appropriate estimated acquisition cost. (*Id.* at 202:15-4.) According to Mr. Gorospe, states did not have to use AWP in their estimated acquisition cost formula and were free to establish estimated acquisition costs in different ways. (*Id.* at 203:6-11.)

20. According to Mr. Scully, CMS educated state governors and Medicaid directors regarding Medicaid drug reimbursement levels, but ultimately it was the state's decision as to what level the state would reimburse providers. Mr. Scully testified:

A. I just told you, I spoke at many state conferences, and I talked to many governors and Medicaid directors about trying to lower – I spoke at many state conferences and many governors about trying to adjust their Medicaid drug reimbursement. But they had the discretion to do that.

And governors and Medicaid directors have to deal with community pharmacists, and local pharmacists, and local politics, and that's not the role of, in this administration, anyway, the role of the CMS administrator to go in and tell states what they have to pay. We spent a lot of time trying to educate them.

(7/13/2007 Scully Dep. at 636:17-637:8, Ex. 65.)

21. Furthermore, Mr. Scully testified that it was CMS's policy to let the states make their own determination of Medicaid drug payment rates. Mr. Scully testified that it was up to the states' discretion whether to include a discount from published AWP's of only 10% when studies showed much higher average discounts from published AWP. (5/15/2007 Scully Dep. at 209:11-210:15, Ex. 64.) Mr. Scully testified:

Q. And from CMS's perspective, it would be okay if states used AWP minus 10 percent as a reimbursement level, even though

CMS and the state knew that the actual acquisition cost was more like AWP minus 40 percent?

MR. GOBENA: Object to the form.

MR. BREEN: Object to the form.

MS. MILLER: Object to the form.

BY MR. DALY: Q. Go ahead.

A. I'm certain that we tried to educate them state by state as to reference documents as to what reasonable prices were. But the pricing policy whether it's nursing homes, hospitals, providers was as long as it wasn't unreasonable and as long as it wasn't part of a refinancing money churning scam to avoid putting up state dollars, it was up to the discretion of the state what they negotiate with providers in the Medicaid program, including drugs, unless Congress told us otherwise, which they never did that I'm aware of.

22. On December 6, 2007, the DOJ filed a response to a request for a preliminary injunction to the enforcement of the certain rules that CMS had proposed to implement provisions of Deficit Reduction Act of 2005 related to the calculation of Federal Upper Limits. (Ex. 70 (Abbott Ex. 1150).) In its response, under a section titled "The Medicaid Payment Framework Prior to the Deficit Reduction Act of 2005," the DOJ stated: "States – not the federal government – set the rate at which they pay pharmacies and other healthcare providers for Medicaid-covered products and services, and the federal government provides federal financial participation (FFP) to states to cover a portion of those costs." (*Id.* at 4.) The DOJ's brief further stated:

As discussed above, Medicaid is a cooperative program between the states and the federal government pursuant to which the federal government helps states provide covered services to Medicaid-eligible beneficiaries. The federal government pays nothing 10 pharmacies for the prescription drugs those pharmacies distribute to Medicaid patients, does not dictate the formulas states may use to determine the amount they will pay pharmacies, and does not prescribe limits on state payments to pharmacies."

(*Id.* at 13.) The DOJ brief also stated: “First, one of the broad federal requirements for state payment rates is that State Plans must ‘assure that payments ... are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population.’ 42 U.S.C. § 1396a(a)(30)(A).” (*Id.* at 14.)

23. Abbott has proffered expert opinion testimony from Louis Rossiter, a Public Policy Professor at the College of William & Mary. (Ex. 71 (Rossiter Report at ¶ 1).) Dr. Rossiter previously served as Secretary of Health and Human Resources for the Commonwealth of Virginia and as a Senior Policy Advisor to the Administrator, Center for Medicare & Medicaid Services. (*Id.*) Dr. Rossiter provided, among other opinions, the following opinions regarding Medicaid policy:

- “Medicaid policy is primarily driven by the individual states, and there is substantial variation in eligibility, benefits, and provider payment and rates of payment from one state to the next.”

(Rossiter Report at ¶ 17.)

- “Although the Medicaid program is jointly financed by the federal government and the states, with the federal government matching state spending according to a formula, Medicaid was designed to provide states with the ability and substantial flexibility to respond to local conditions and needs. States have day-to-day responsibility for running the program, within the broad framework of federal laws and policies. Some services are required by the federal government, and others are offered at state option, including prescription drug coverage. States are authorized to and routinely set limits on the “amount, duration, and scope” of benefits. States are also responsible for determining the specific method that will be used to pay providers, including pharmacy providers, for services provided to Medicaid recipients.”

(Rossiter Report at ¶ 18.)

24. In the 1987 Medicaid regulations, 42 C.F.R. § 447.331, HHS established “aggregate upper limits of payment.” For multiple-source drugs for which CMS established “upper limits” pursuant to 42 C.F.R. § 447.332, the 1987 Medicaid regulations provided that the

state Medicaid agency's payments were not to exceed, "in the aggregate," payment levels determined by applying for each drug entity a reasonable dispensing fee established by the agency plus the upper limit amount for ingredient cost established by HCFA. (Ex. 60 (Abbott Ex. 284), at 42 C.F.R. § 447.332 (b).)

25. Multiple-source drugs for which CMS did not establish upper limits pursuant to 42 C.F.R. § 447.332 were treated as "other drugs." (*Id.* at 42 C.F.R. § 447.332 (a).) Similar to multiple-source drugs for which CMS did establish upper limits, a state agency's payment for "other drugs" was to measured "in the aggregate." For these drugs, the state agency's were not to "exceed, in the aggregate, payment levels that the agency has determined by applying the lower of — (1) Estimated acquisition cost plus reasonable dispensing fees established by the agency; or (2) Providers' usual and customary charges to the general public." (42 C.F.R. § 331.(b).)

26. The preamble to the 1987 Medicaid regulations includes the following language:

- "[I]t was our intent to permit State agencies to exercise maximum flexibility in designing a payment system subject only to the maximum payment levels established by this regulation."

(Ex. 60 (Abbott Ex. 284) at 28651.)

- "State agencies are encouraged to exercise maximum flexibility in establishing their own payment methodologies."

(*Id.* at 28653.)

- "Under these rules, the Federal requirement for States to use the EAC method of payment will be eliminated. However, because the rule merely establishes an upper limit concept and does not describe the specific methodology for payment, State agencies may continue their practice of establishing EACs for the ingredient costs and adding to it a dispensing fee. Such practices will be acceptable, as will a system of establishing charge/payment screens based on Statewide or regional customary and usual prices."

(*Id.* at 28654.)

27. On July 31, 1987, HHS issued a news release describing the 1987 Medicaid regulations. (Ex. 72 (HHC002-0524-25 ).) That news release contained the following language:

The new procedures will apply to state drug expenditures for each of these categories on an aggregate basis. That is, the individual prices set [by the] Medicaid agencies, may exceed federal levels for some drugs, but will be less than federal levels for other to offset the increases and to meet the aggregate expenditures test.

States will not need to submit detailed accountings to HCFA to receive approval of the payment system in the state Medicaid plans. Instead, approval will be based on assurances by the state that the regulatory requirements are met.

(*Id.* at HHC002-0025.)

28. In August 1987 Don Newman, Under Secretary of DHHS, wrote an article describing the 1987 Medicaid regulations. Mr. Newman stated:

The new [regulatory] procedures will apply to State drug expenditures for each of these categories on an aggregate basis. That is, the individual prices set by State Medicaid agencies may exceed federal levels for some drugs. However, prices will need to be less than Federal estimated acquisition costs levels for others to [] offset the increases and to meet the aggregate expenditures test.

(Ex. 73, Don M. Newman, Drug Topics, August 1987, at 5 (HHC902-1062-67).)

29. CMS official Dennis Smith testified indicating that states were permitted under the 1987 Medicaid regulations to pay more than estimated acquisition cost for individual drugs, as long as payments were appropriate “in the aggregate”:

Q. What does it mean for the payment limitation to be in the aggregate rather than on a drug by drug basis?

A. I think precisely that, all of them put together.

Q. And so a state could decide to pay more for one drug, less for another drug, but as long as you add them all up in the end in the aggregate it is at the appropriate level, that would meet federal regulatory requirements, right?

A. That is correct. States could pay even more if they wanted to.  
But this is a restriction of how much we would be willing to match.

(2/26/2008 Smith Dep. at 149:8-22, Ex. 63.)

30. CMS designated Larry Reed to provide Rule 30(b)(6) testimony on the following topic: "From 1991 to 2001, with respect to Medicaid, how CMS defined and implemented 'estimated acquisition costs,' and whether in general (not in detail as to each state or each year) CMS believed that the formula in the state plans would result in payment for drugs at the estimated acquisition cost of those drugs." (3/20/2008, Reed 30(b)(6) Dep. at 23:13-32:18, Ex. 74; Ex. 75 (Abbott Ex. 757).) On behalf of CMS, Mr. Reed provided the following Rule 30(b)(6) testimony regarding the 1987 Medicaid regulations:

Q. Well, let me ask you this. As you sit here today can you point me to any federal regulation that requires -- that prevents a state from paying more than its best estimate on a particular drug?

MR. WINGET-HERNANDEZ: Objection, form.

A. There is no other federal regulation that I'm aware of that would address EAC other than that point we discussed this morning.

Q. So the answer to my question would be you cannot point me to any federal regulation on that?

MR. WINGET-HERNANDEZ: Objection, form.

A. I believe that's what I would say.

(3/20/2008 Reed 30(b)(6) Dep. at 77:7-18, Ex. 74.)

\* \* \* \* \*

Q. The question is is there anything in the federal regulations that would prevent a state Medicaid pharmacy administrator such as Mr. Sullivan from paying a margin or a profit above acquisition cost for generic drugs?

A. The provision in the federal regulation on EAC being the best estimate I think would be the answer to that question, that -- to the

extent that that EAC had built within it its estimate a profit margin, that could be possible.

(*Id.* at 90:1-10.)

31. Mr. Reed also provided the following Rule 30(b)(6) testimony:

Q. And as you sit here today are you aware of any evidence that would support the allegation that from 1991 through 2001 the state formula did not result in payments for drugs at estimated acquisition cost?

MR. AZORSKY: Objection to form.

A. Again, I can only state what I've said before, that we believe that those formula in the state plans resulted in payments for drugs at the EAC of those drugs.

Q. Even today?

A. Yes.

(*Id.* at 218:14-219:3.)

32. James Parker serves as the Deputy Administrator for the Illinois Department of Healthcare and Family Services in the Division of Medical Programs. (11/18/2008 Parker Dep. at 17:10-16, Ex. 16.) Mr. Parker testified that, consistent with the 1987 Medicaid regulations, Illinois was permitted to pay more than the EAC of a particular drug. (*Id.* at 245:1-8 (“Yes, it does appear that you could pay on a particular drug higher than Estimated Acquisition Cost.”).)

33. In 1983, HHS established a Task Force to review HHS's Medicaid drug reimbursement regulations. The work of the Task Force eventually culminated in the adoption of the 1987 Medicaid regulations. Dr. Robert B. Helms, the Assistant Secretary for Planning and Evaluation at HHS, was appointed to chair that Task Force. (Ex. 76 (Abbott MD Ex. 5).) Dr. Helms prepared an expert report on behalf of Defendants in connection with these cases, wherein he provided the following explanation of why the 1987 Medicaid regulations measured state Medicaid payments “in the aggregate”:

In coming to the recommendations that eventually led to the 1987 regulations, the Medicaid task force built upon preexisting reimbursement terminology and structures. We decided to maintain the existing structure of an ingredient cost, whether based on an “Estimated Acquisition Cost” or a specifically prescribed limit, and a separate dispensing fee that theoretically included profit. We also recognized that existing state practice utilized cross-subsidization. Accordingly, we included language that expressly allowed the existing practice of cross-subsidization to continue. This language consisted of including the term “in the aggregate” when describing the upper limits on payment for ingredient costs and dispensing fees. In other words, payment at the overall level (or “in the aggregate”) was not to exceed the sum of an ingredient cost and a reasonable dispensing fee with regard to all the drugs used in the state program. But we left it to the states to decide whether they wanted to accomplish that through offsets and cross-subsidization. So long as the overall level of payment was reasonable, our federal policy goals were satisfied. We explicitly considered and rejected the alternative approach commonly used in public utility regulation to rigorously define the accounting methodology for each separate component of the aggregate total.

(Ex. 77 at ¶ 30 (Expert Report of Robert B. Helms).)

34. On or around September 28, 1987, Dr. Helms delivered a speech at the Symposium on the New Medicaid Regulations on Drug Reimbursement titled “The Complicated History of Medicaid Regulations on Drug Reimbursement.” (Ex. 76 (Abbott MD Ex. 5).) A document reflecting that speech includes the following language:

[T]he Inspector General of HHS issued a report claiming that published wholesale prices were on average about 16% higher than prices actually paid, and that upwards of \$50 million a year in single-source savings could be obtained. This report was followed by a sporadic effort to encourage states to create a new set of surveys covering wholesale prices (and a crescendo of complaints over both the validity of the IG estimates (the report exaggerated somewhat the discrepancies in prices) and its failure to recognize that many states had deliberately held down dispensing fees as a quid pro quo for known “fat” in published wholesale prices;

(*Id.* at 4-5.)

35. The HHS Departmental Appeals Board (“HHS DAB”) resolves disputes between HHS and outside parties such as state agencies, Head Start grantees, universities, nursing homes, doctors, and Medicare beneficiaries relating to HHS programs. (<http://www.hhs.gov/dab/> last accessed on August 25, 2009.) As stated on its website, DAB’s decisions represent the “final decision” of HHS. (*Id.*)

36. On March 18, 1992, the HHS DAB issued a decision, No. 1315, interpreting the “in the aggregate” provision of the 1987 Medicaid regulations. (Ex. 78 (Abbott Ex. 1153).) HHS DAB’s Decision No. 1315 contained the following language:

Section 447.333(b) of 42 C.F.R. provides in pertinent part that a state’s drug payments may not exceed “in the aggregate” the specific limits established by HCFA for each drug plus a reasonable dispensing fee for each drug. Since the focus of the regulations is on a state’s overall payment level, the State could reasonably have concluded that it could offset a lower than reasonable dispensing fee with ingredient costs which were higher than HCFA’s specific limits as well as higher than the costs to the pharmacies themselves.

The preamble to the 1987 regulations provides further support for the State’s position. The preamble indicates that HCFA set an aggregate limit to give the states flexibility to adopt alternative methods of reimbursement. Contrary to HCFA’s position, it is likely that HCFA intended a state to have flexibility in how it determined its overall payments and not merely with respect to the pricing of ingredient costs since HCFA recognized that some states paid pharmacies without separately identifying a dispensing fee.

(*Id.* at 8.)

HHS DAB’s Decision No. 1315 also referenced an earlier ruling, which stated:

The regulation can reasonably be read to permit states to pay more than an appropriately determined EAC for drug ingredient cost, but less than a reasonable dispensing fee, so long as the payments did not, in the aggregate, exceed the upper limit.

(*Id.* at 12.)

## **B. State Regulations And Statutes**

37. Most states defined AWP in their state plans to refer to prices found in the compendia. For example:

(a) Alaska's State Plan, effective February 1, 1989, defined EAC as the "average wholesale price published in the American Druggist Blue Book, as updated monthly, less 5 percent of that amount." (Ex. 79 (HHC 020-1268).)

(b) California's State Plan, effective March 19, 1991, read:

Prior to October 16, 1989, "[EAC]" of the drug product dispensed for most drugs meant the average wholes price (AWP) of a standard package size (e.g., 100s or pints) as listed in a price reference source such as the American Druggist Blue Book. Effective October 16, 1989, the State Agency implemented regulation changes which redefined the Average Wholesale Price (AWP) component of EAC to be AWP minus 5 percent.

(Ex. 79 (HHC016-0695).)

(c) Colorado's State Plan, effective July 1, 1990, read:

[EAC] is the lower of the modified Average Wholesale Price or the modified direct cost to the wholesaler or pharmacy. The modified Average Wholesale Price is Average Wholesale Price (as determined from the First Data Bank automated price updating service) less 10.00%, except for certain high volume drugs single source drugs or multi-source drugs with bioequivalence problems.

(Ex. 79 (HHC013-1134).)

(d) North Dakota's State Plan, effective July 1, 1990, read:

[EAC] will be this agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler. EAC is defined as the Average Wholesale Price (AWP) minus ten percent (10%) as determined from Blue Book on a bimonthly basis.

(Ex. 79 (HHC013-0351).)

(e) The District of Columbia's State Plan, effective August 1, 1997, read:

The average wholesale price shall be the price, at the time of service, set forth in the most recent listing supplied to the

Department by the First Data Bank National Drug Data File Services.

(Ex. 79 (HHD039-0024).)

(f) Florida's State Plan, effective July 2001, read:

Source of Prices. Medicaid uses ingredient costs that are supplied and updated every week by the First Databank's National Drug File Data electronic service."

(Ex. 79 (EXP USABT-DUG 068829).)

(g) Hawaii's State Plan, effective April 1, 1992, read:

"The [EAC] for purposes of this section is defined as the average wholesale price minus 10.5%. Average wholesale price will be derived from the most commonly used package size listed in the Bluebook."

(Ex. 79 (HHD041-0081).)

(h) Iowa's State Plan, effective July 1, 1990, read: "[EAC] is defined as the average wholesale price as published by First Data Bank less 10%."

(Ex. 79 (HHD077-0069).)

(i) Louisiana's State Plan, effective July 1, 1992, read: "Average Wholesale Price" (AWP) means the wholesale price of a drug product as reported to Medicaid by one or more national compendia on a weekly basis." (Ex. 79 (HHD076-0040).)

(j) Mississippi's State Plan, effective July 1, 1991, provided:

The best estimate is based on the average wholesale price (AWP) less 10 percent. For the AWP information the Division uses the Red Book, Medispan, Manufacturer's List Price.

(Ex. 79 (EXP USABT-DUG 069243).)

(k) Missouri's State Plan, effective September 17, 1991, based its reimbursement on "Average Wholesale Price (AWP) as furnished by the state's contracted agent less 10.43%" (Ex. 79 (HHD077-0128).)

(l) Nevada's State Plan, effective January 1, 1995, defined EAC as "Average Wholesale Price (AWP) as indicated on the current listing provided by First Data Bank, minus ten (10) percent." (Ex. 79 (HHD041-0247).)

(m) New Jersey's State Plan, effective 1991 and 1996, referred to the "current national compendia" in defining EAC:

State Plan effective February 26, 1991: "The [EAC] herein defined as lower of the Average Wholesale Price (AWP) listed for the most frequently purchased package size ... in current national compendia."

(Ex. 79 (HHD037-0129).)

State Plan effective October 21, 1996: "... the [EAC], which is defined as the average wholesale price (AWP) listed for the package size (billed to the New Jersey Medicaid program), in current national price compendia or other appropriate sources (such as the First Data Bank (FDB) reference drug file contractor), and their supplements, minus a 10 percent volume discount."

(Ex. 79 (HHD037-0121).)

(n) North Carolina's State Plan, effective August 17, 1992, provided: "For the AWP information the Division uses the First Databank Price Update Service, manufacturer's price list, or other nationally published sources." (Ex. 79 (EXP USABT-DUG 069508).)

(o) North Dakota's State Plan, effective July 1, 1990, read: "EAC is defined as the Average Wholesale Price (AWP) minus ten percent (10%) as determined from Blue Book on a bimonthly basis." (Ex. 79 (HHD038-0034).)

(p) Oklahoma's State Plan, effective March 1, 1990, read:

The EAC to be used for the purchase of prescription drug products is established at a percentage of the Average Wholesale Price (AWP) as defined by the American Druggist Blue Book."

(Ex. 79 (HHD076-0084).)

(q) Oregon's State Plan, effective April 1, 1991, read: "The direct price from manufacturer and the average wholesale price is determined using information furnished by the DHR's drug price data base contractor." (Ex. 79 (HHD074-0266).)

(r) Pennsylvania's State Plan, effective October 1, 1995, read: "The EAC established by the Department as the current AWP found in the Department's pricing service ... minus 10 percent." (Ex. 79 (HHC007-0980).)

(s) Rhode Island's State Plan, effective January 1, 1995, defined EAC as "the manufacturer's reported [WAC] plus a 10% markup." (Ex. 79 (HHD040-0061).)

(t) South Carolina's State Plan, effective July 1, 1990, read: "The AWP used in calculating the SEAC is furnished by a contracted pricing source." (Ex. 79 (EXP USABT-DUG 069604).)

(u) South Dakota's State Plan, effective January 1, 1990, provided: "The EAC is established first utilizing the monthly Medispan listing, or for items not on the Medispan list, the RedBook ..." (Ex. 79 (HHD038-0492).)

(v) Utah's State Plan, effective January 1, 1989, contained the following definition of Average Wholesale Price:

The Average Wholesale Price (AWP) is determined for each drug by the Utah contract with American Druggist, Blue Book First Data Bank. . . . First Data Bank uses AWP from wholesalers in many states for determining AWP in specific regions.

(Ex. 79 (HHD038-0535).)

(w) Virginia's State Plan, effective April 1, 1993, provided:

The [EAC] shall be based on the published Average Wholesale Price (AWP) minus a percent discount established by the following methodology ....

(Ex. 79 (VA production 00001043).)

(x) Washington's State Plan, effective October 1, 1993, provided:

Payments for brand name and/or single source drugs are based on Average Wholesale Price (AWP) less a specified percentage. The Average Wholesale Price is determined using price information published by the Medicaid Management Information System's Drug Pricing File contractor. The percentage discount may vary, based on results of periodic reviews of average wholesale price and estimated acquisition cost.

(Ex. 79 (HHC020-1733).)

(y) West Virginia's State Plan, effective January 1, 1998, read: "The reference price for average wholesale price (AWP) will be as listed in First Databank or other designated National Drug Pricing Publications." (Ex. 79 (HHD039-0546).)

(z) Wisconsin's State Plan, effective July 1, 2001, provided:

"Drug prices to which the discounted published average wholesale price applies will be determined by applying a [11.25] percent discount to the AWP's listed in the First Data Bank Blue Book."

(Ex. 79 (HHD075-0404).)

(aa) Wyoming's State Plan, effective June 22, 1991, contained the following definition of AWP: "The Average Wholesale Price (AWP) is determined for each drug through Wyoming's fiscal agent contract with Blue Book First Data Bank, National Drug Data File."

(Ex. 79 (HHD038-0841).)

**C. Margins On Ingredient Cost Were Expected And Permitted**

38. Numerous state officials testified that they understood that their state payment methodologies for drugs resulted in the payment of a margin, or profit, on ingredient costs for generic drugs. For example:

(a) Jerry Dubberly, formerly the Pharmacy Director of Georgia Medicaid and currently the Chief of the Division of Medical Assistance, testified:

Q. Mr. Robben asked you some questions about the interplay between the -- the reimbursement of ingredient costs and the reimbursement for dispensing costs. Do you remember those questions, sir?

A. Yes.

Q. And I believe you said that -- that the Georgia Medicaid program understood that -- that they were providing a -- a profit margin to providers in reimbursing them for the ingredient costs; is that right?

MR. LAVINE: Object to form.

A. Yes. I acknowledged that there was profit margin in the current ingredient cost formula.

Q. (By Mr. Cole) And that if -- if that margin were to be eliminated, then Georgia would have to pay a higher dispensing fee to providers to make up for the lost margin on the ingredient cost side; is that fair?

MR. LAVINE: Object to form.

A. That's fair.

(12/15/08 Dubberly Dep. at 314:3-315:2, Ex. 24.)

(b) Louisiana Medicaid's M.J. Terrebonne testified:

Q. Do you think for generic drugs that you are paying actual acquisition cost to providers?

A. No.

\* \* \*

[DOJ counsel] Q. And that under the [Louisiana] state plan, the actual cost of dispensing a drug and any profit to a provider was to be reflected in the dispensing fee?

MR. TORBORG: Object to the form.

THE WITNESS: No. There is some profit review in the ingredient cost as well.

(3/31/2008 Terrebonne Dep. at 228:13-15, 270:14-271:6, Ex. 25.)

(c) Sandra Kramer spent twenty-one years as a policy analyst at Michigan Medicaid, researching reimbursement methodologies and helping draft the state plan amendments dealing with drug payments to providers. (3/25/2008 Kramer Dep. at 31:20-36:18, Ex. 4.) She testified that for generic drugs, providers would be paid greater than acquisition costs:

Q. For generic drugs, assuming the screens did not come into play, assuming it wasn't going to reach the MAC, did you understand that certain providers would be paid greater than their acquisition costs when Michigan used an EAC system?

A. Yeah.

(*Id.* at 111:19-112:2.)

\* \* \*

And if the actual acquisition costs, in fact, were lower than the AWP minus discount, then the provider would get some sort of margin on their drug; is that right?

A. Right.

(*Id.* at 176:22-177:4.)

(d) Ed Vaccaro formerly served as both the Chief Pharmaceutical Services Consultant and Assistant Director of Office of Utilization Management for New Jersey Medicaid. Ed Vaccaro testified:

Q. So during that period of time, the last 24 years, New Jersey has known that it is paying Medicaid ingredient cost payments that are greater than the actual acquisition costs found in those OIG reports; right?

MS. YAVELBERG: Objection, form.

THE WITNESS: Yes.

(12/3/2008 Vaccaro Dep. 650:11-17, Ex. 80.)

(e) Rhode Island's Paula Avarista, Rhode Island Medicaid's Chief of Pharmacy, testified:

Q. So is it your understanding that the goal of Rhode Island Medicaid was to identify an ingredient cost that had some provision for markup from the price at which the pharmacies actually purchased the drug?

MS. BAUM: Objection.

THE WITNESS: Yes.

BY MS. RANKIN:

Q. And has that always been your understanding Rhode Island Medicaid program's efforts with respect to identifying ingredient cost component for Medicaid reimbursement, that they would want to provide some margin over the actual purchase price for pharmacy providers?

A. Yes.

Q. And just to be clear, we are talking just about the ingredient cost component of the reimbursement, right, not the dispensing fee component?

A. Yes.

Q. The dispensing fee would be an additional reimbursement component in addition to the ingredient cost component which has some markup over actual acquisition cost?

A. Yes.

(12/4/2008 Avarista Dep. at 130:1-131:3, Ex. 81.)

(f) Leo Sullivan, the former Director of Pharmacy Services for Tennessee Medicaid from 1989 to 2004, testified:

Q. And if you look further down the paragraph, the carryover paragraph on page 110, the second page of the exhibit, the sentence is that starts with More importantly. Do you see that?

A. Yes.

Q. It says, More importantly, in view of the Medicaid program's legal obligation to reimburse true provider acquisition costs, such an effort by the states to ensure payment is based on actual prices, it is mandatory. Do you see that?

A. Yeah, I see it.

Q. Do you recall a discussion at any meeting that state Medicaid programs have a legal obligation?

A. No. No.

Q. Was that consistent with your understanding of what was required by the state, Tennessee?

A. No.

Q. And what was your understanding of what was required?

A. Well, I mean why -- if there was a legal obligation to only reimburse true provider acquisition costs, then why do we go through the trouble of submitting state plans? You tell me what reimbursement is going to be.

Q. What do you mean by that?

A. Well, why would -- if the federal government is saying you are legally obliged to pay no more than cost, then you tell me what cost is. Why do I bother submitting a state plan amendment that says I'm going to apply the lesser of this, or AWP minus that, or this or that or the other, that you approve if I'm legally obliged to paying cost. Obviously -- I mean you don't know what cost is. You can't -- or else you would dictate it. Does that make sense?

Q. A little bit.

A. That's -- it's impossible to enforce, and I don't ever remember anybody ever telling me, Leo, you got a legal obligation to only pay true provider's cost. You do that and you won't have a program.

(3/12/2008 Sullivan Dep. at 217:16-219:17, Ex. 1.)

39. CMS's Deirdre Duzor testified that CMS had concerns that reimbursing at actual average acquisition cost would pose access problems:

Q. Here you were proposing to accept any aggregate decrease in ingredient cost reimbursement as long as it was no lower than the findings of OIG's reports as long as the state can demonstrate adequate access; is that right?

\* \* \*

A. Yes, that's what it says.

Q. Why did you cap the decrease at OIG's findings?

A. Because they would not be arbitrary for us to come up with -- for us to make up a number would appear to be arbitrary. We were not trying to be arbitrary. However, we were concerned, as the last phrase indicates, that they may -- the rates suggested by the OIG, again, they were an average, they were 200 and some pharmacies in eight states and only so many drugs -- that they may be too low and we were concerned that states would need to be able to demonstrate that they could maintain adequate access for Medicaid beneficiaries.

Q. So you were concerned that paying pharmacies the average amount of discount that OIG had found would not provide incentive necessary to ensure access; is that fair to say?

\* \* \*

A. We wanted to require that, again, the states propose their reimbursement rates, they also would need to demonstrate to us that those rates were sufficient maintain adequate access.

Q. And this would have to be an affirmative showing by the state? They couldn't go to OIG's levels unless they made an affirmative showing of adequate access; is that right?

\* \* \*

A. They would need to explain to us how they believed they could maintain adequate access. It's the classic policy question in terms of reimbursement.

Q. What do you mean by that, the classic policy question?

A. If the reimbursement is so low that you no longer have providers in your program, you're not helping anybody out.

Q. Did CMS want to see states reimbursing at an actual average acquisition cost for providers?

\* \* \*

A. CMS was interested in appropriate payment, you know, for pharmacies such that they would stay in the program.

Q. Let me see if I can ask it again. Did CMS want to see states reimbursing at an actual average of acquisition cost for providers --

\* \* \*

Q. -- yes or no?

A. I just don't know that it's quite that simple as a yes or no.

Q. Why is it not that simple?

A. Because you have to make sure that pharmacies are willing to serve Medicaid beneficiaries at that rate of payment.

Q. And is it fair to say based on your reservation that it's not that simple that CMS's concern that payment at an actual average is not sufficient to ensure access?

\* \* \*

A. We did not know the answer to that question, which is why, again, we would say to the state you need to provide us the evidence. You're out there paying providers, enrolling them in the program. We're reviewing that at the national level.

Q. But fair to say that CMS would have concerns that payment at an actual average of ingredient cost would not provide incentives to ensure adequate access?

\* \* \*

A. We wanted to ensure that -- right -- that that would not be an adverse impact of --

Q. So you had concerns?

A. That -- yes, that potentially that could cause an access problem.

\* \* \*

Q. But combined ingredient cost and dispensing fees had to be sufficient to ensure access to care?

A. Yes.

(2/27/08 Duzor Dep. at 319-24, Ex. 82.)

**D. Assessing Margins**

40. In December of 2004, the Congressional Budget Office issued a report titled “Medicaid’s Reimbursements to Pharmacies for Prescription Drugs.” (Ex. 83 (Abbott Ex. 475).)

That report included the following statements:

- “For each prescription that a pharmacy fills under the program, Medicaid pays the pharmacy an amount meant to cover both the cost of acquiring the drug from the manufacturer and the cost of distributing and dispensing it. That ‘markup’ that Medicaid pays is defined in this paper as the dollar difference between the total amount that Medicaid pays the pharmacy for each prescription and the amount that the pharmacy or wholesaler pays the manufacturer for the drug.”
- **“Measuring Markups.** In addition to dollar terms, the difference between the amount that Medicaid pays pharmacies for prescription drugs and the amount that manufacturers charge pharmacies for the drugs can be expressed in percentage terms as a margin (or gross margin)-that is, the difference between what Medicaid pays a pharmacy and the cost of acquiring the drug from the manufacturer, divided by Medicaid’s payment. The two measures-the markup and the margin-yield very different pictures. For example, the percentage margin retained by pharmacies and wholesalers has been about the same in recent years for both newer and older generic drugs, but because Medicaid’s reimbursements for newer generic drugs have been higher, the dollar markup on them has been more than three times that on older generic drugs. Because pharmacies’ cost of filling a prescription is largely unrelated to the cost of acquiring its ingredients or the size of the prescription, the dollar markup is a better indicator of the size or adequacy of Medicaid’s reimbursements to pharmacies than is the percentage margin. The time a pharmacist spends filling a prescription is generally unrelated to the drug’s cost and is only marginally greater for larger prescriptions than for smaller ones. Moreover, the shelf space required to store a \$5 pill is no different from that required for a \$1 pill.”

(*Id.* at 1, 3.)

41. State and federal officials testified regarding how they viewed the margins paid on ingredient cost payments.

(a) Tennessee’s Leo Sullivan testified:

Q. With respect to that profit component, should your testimony be understood to mean that any level of profit that might be generated by the application of a spread, or the existence of a spread, was in

accordance with the fundamental principles that Medicaid, the Medicaid program in Tennessee was operating under?

MR. TORBORG: Object to form.

A. It would, it would depend on the level of that profit.

BY MR. DRAYCOTT:

Q. For example, should we understand your testimony to be that if there was a thousand percent profit, for example, on a bag of water, that wouldn't necessarily, by virtue of your testimony, be something that should be considered to be consistent with the principles, the fundamental principles that operated with respect to Tennessee Medicaid at the time?

A. I would answer that question maybe two different ways. First off, depending on the cost of a product and looking at whatever the dispensing fee is, it could be that a thousand percent profit is a couple of dollars, okay? So it doesn't look quite so ridiculous, so unacceptable, from a taxpayer's standpoint. When it, when it is, when you are talking about huge money, then that's when I failed. So to answer your question, it may be appropriate in some small percentage of cases that it would be a thousand percent profit, but I would, I would agree that, generally speaking, if thousands of percents of profits are being made on ingredient costs on a drug dispensed in the Medicaid program that I was overseeing, that I've made a mistake somehow, and it shouldn't be that way.

(3/12/08 Sullivan Dep. at 312:14-314:6, Ex. 1.)

\* \* \*

Q. And asked you if your testimony should be seen by the jury in this case as endorsing or not endorsing such spreads and whether or not payment of a thousand percent spreads would be appropriate. Do you recall that?

A. Yes.

Q. Do you believe the better way to look at the appropriateness of a Medicaid program paying a margin or spread on a drug is the dollar value of the spread rather than the percentage?

A. You know, at certain ends of the scale, both need to be looked at, but I would agree that the dollar difference is something that needs to be looked at first, because, you know, a thousand percent

makes headlines but doesn't mean anything if you don't have a dollar amount affixed to it.

Q. And do you think expressing spreads in terms of a percentage, like Mr. Draycott did, can oftentimes –

MR. DRAYCOTT: Objection.

BY MR. TORBORG:

Q. -- misconvey the real spread that's being paid by a Medicaid program?

A. That's possible.

Q. It may be that a spread of a thousand percent might be an appropriate amount to pay, depending on the facts and circumstances of both the drug involved and the services involved in paying those, dispensing those drugs?

A. It gets back to partially this thought process of not wanting the drug to merely be a commodity. So if, for example, your dispensing fee is limited to 2.50 and the drug -- and it is a very inexpensive drug, and it does cost 6 bucks to dispense that drug to a Medicaid patient, ratcheting down reimbursement based on a percentage of profit on the ingredients side may make it prohibitive for that provider to dispense the product. If that makes sense.

(*Id.* at 327:15-329:9.)

(b) Minnesota's Cody Wiberg testified:

Q. So 25 cents is what the State Medicaid Program chose to pay for that 6 cent pill, right?

A. That's correct.

Q. Isn't that about a 400 percent spread, between 6 and 25?

A. Well, again, you can't -- people don't spend percentages. They spend dollars.

(3/14/2008 Wiberg Dep. at 357:9-15, Ex. 68.)

\* \* \*

Q. But in these generics MACs that you're setting are shooting for a dollar amount spread –

A. Right.

Q. -- not necessarily for a correct percentage spread, right?

A. That's correct.

Q. And the correct percentage could be a thousand, could be 2,000, could be 1 percent, depending upon the starting cost of the product, right?

A. Yes, we are searching for a dollar spread, not a percent spread.

(*Id.* at 360:2-13.)

\* \* \*

Q. If the actual acquisition cost were about a dollar.

A. About a dollar.

Q. The AWP was about \$9, and the AWP minus 9 percent came out to about \$8, such that the spread was about \$7. That would be consistent with the goals of the Medicaid program, correct?

A. Yes.

(*Id.* at 361:5-12.)

(c) Louisiana Medicaid's M.J. Terrebonne testified:

Q. Does a payment of a margin of \$8 to \$12 per prescription, Ms. Terrebonne, concern you at all?

MR. FAUCI: Object to the form.

THE WITNESS: I would say no, not based on the current reimbursement methodology.

BY MR. TORBORG

Q. And why is that?

A. Because that's perhaps the pharmacists are making a profit on the ingredient cost rather than the dispensing fee, because the dispensing fee may be lower than their ingredient cost.

(3/31/2008 Terrebonne Dep. at 216:5-16, Ex. 25.)

\* \* \*

Q. If I told you that the average margin on ingredient cost reimbursement, assuming reimbursement was actually based on the AWP for these drugs, was in the range of \$8 to \$10 through the 1990s, would that offend you?

MR. FAUCI: Object to the form.

THE WITNESS: Would that offend me?

BY MR. TORBORG:

Q. Yes. Would you say, "We have been cheated? We have overpaid"?

MR. FAUCI: Object to the form.

THE WITNESS: No.

(*Id.* at 218:13-219:2)

(d) CMS's Dierdre Duzor testified:

Q. And then the next paragraph states "Because pharmacies' cost of filling a prescription is largely unrelated to the cost for acquiring its ingredients or the size of the prescription, the dollar markup is a better indicator of the size or adequacy of Medicaid's reimbursements to pharmacies than is the percentage margin." Do you see that?

A. Yes, I do.

Q. Do you agree with that?

A. Yeah. I think statistically you're looking at numbers, yes. It tells -- it's more descriptive of the situation than a dollar figure.

Q. This is indicating that the dollar markup is the better indicator.

A. Oh, yeah. Yes, I do understand that.

Q. And do you agree with that?

A. Yes. Because if you have a prescription that's a dollar and you have a hundred percent markup, that's only another dollar. That's all it is.

Q. Pharmacies are paid in dollars, not percentages; is that fair to say?

A. That's fair to say.

(2/27/2008 Duzor Dep. at 487:6-488:8, Ex. 82.)

42. In a January 2008 report, OIG found that the estimated dollar difference per prescription between Medicare Part D payments and drug acquisition costs was around \$9 for both generic and branded drugs. (Ex. 84 (Abbott Ex. 477).) In its response to that report, CMS included the following statement:

The report also found that the percentage differences between Part D payments and drug acquisition costs were more than nine times higher for generic drugs than for brand-name drugs. Clinically appropriate generic prescribing is one of the key ways in which the Part D program is able to provide high quality coverage at a reasonable cost to both beneficiaries and the government. We fully encourage the use of generic drugs since their use provides good value to both the beneficiary and the taxpayer, and we note that incentives are aligned to encourage promotion of generics by community pharmacies.

(*Id.* at Appendix G.)

**E. Promoting Generic Drugs**

43. Numerous state officials testified that they understood that their state payment methodologies for drugs were designed to allow the payment of a margin on ingredient cost to encourage the dispensing of generic drugs. For example:

(a) A 2001 Illinois document contained the following statement:

The [OIG] audit reports that pharmacies can purchase generic and brand name drugs for 65% and 22%, respectively, less than the wholesale price. In this rulemaking, DPA is increasing the percentage deduction from the AWP for generic drugs from 12% to 20% and brand names from 10% to 11%. When deducted from the percentage discount allowed for generic and brand name drugs (64% [sic] and 22%), an overall profit of 44% is made by the pharmacy when generic drugs are dispensed and 11% when brand name drugs are dispensed. *This profit disparity is another way this rule promotes the dispensing of generics over brand names.*

(Ex. 85 (AWP-IL-00008066).)

(b) Tennessee's Leo Sullivan testified:

Q. And when you talk about an incentive you're talking about a financial incentive?

A. Yes.

Q. And what kind of financial incentive would you provide?

A. What, what I tried to make sure I did during this time, this -- I would say from '89 to '94, was, was make sure that there, there was profit to be made for a pharmacist for dispensing generic drugs. It -- these, these folks are pretty savvy. If I'm paying based on what I have submitted to HFCA at the time or CMS today on a state plan that says I will pay AWP minus 10 plus \$4 or 3.91 or \$4, whatever, for a brand name, and I'm setting MAC prices on the corresponding generic that pay the pharmacist his or her net cost, it's not going to take them very long to figure out which drug to process. When they can buy the drug at, you know, AWP minus 18, 20, 22, versus selling it at cost plus a dispensing fee, they're going, they're going to figure that out. And I'm shooting myself in the foot from a budget standpoint, from a, trying to be a responsible manager for the state's taxpayers. So you, you want to -- you want there to be some measure of profit, some incentive over and above a dispensing fee, to incentivize pharmacists to use the generic.

\* \* \*

Q. From your experience, do you think it was well accepted amongst the Medicaid pharmacy administrative community that you would want to pay some profit on multiple-source drugs to incentivize their use?

MS. DAMOULAKIS: Objection.

A. It's just so fundamental, I don't remember discussing that with anybody. I think it's just -- it's something you -- you know, I mean it's just -- makes good sense. I don't, I don't remember any specific discussions with anybody on, you really need to make it profitable so that they will have an incentive to use it.

BY MR. TORBORG:

Q. In your view it's just one of those fundamental tenets of how you operate a state Medicaid pharmacy program.

A. One of my bosses long ago told me that the color of health care is green, and that's true.

(3/12/08 Sullivan Dep. at 60:7-61:14; 62:13-63:10, Ex. 1.)

(c) New Jersey's Mr. Vaccaro testified:

Q. So you testified, you know, just -- just before that there were greater margin percentages between AWP and actual acquisition costs for generics than there are for brands; correct?

A. Correct.

Q. And the AWP for brands tend to be higher than the AWP for generics; correct?

A: Correct.

Q. Okay. So by maintaining -- and I'm -- I'm asking whether this was a policy reason, whether it was a factual actual policy reason, but if you maintained the same reimbursement rates for both generics and brands, would you expect providers -- would that encourage providers to dispense more generics?

A. As it does today, yes.

(12/3/2008 Vaccaro Dep. at 493:3-21, Ex. 80.)

(d) When setting a MAC price, North Dakota Medicaid would consider the amount of profit pharmacists would make for a brand drug and try to include that amount of profit in the MAC price. Brendan Joyce, Administrator of Pharmacy Services, testified:

Q. Okay. I think you mentioned earlier that MAC -- the setting of MAC prices involved consideration of the gross margin that a pharmacy could earn on a brand product. Is that accurate?

A. Yes.

Q. Could you explain that a little further?

A. Well, let's say that a pharmacy earned on average, for the brand products where the AWP was not inflated, earned an average \$12 per prescription.

Q. Okay.

A. Then we would try to do the same on the generic side as a whole.

Q. Okay.

A. To where if we could determine the actual acquisition cost of the product then we could determine how we could get them to make that average of what they had been making on the brand side.

(12/12/2008 Joyce Dep. at 106:16-107:13, Ex. 19.)

(e) Larry Iversen, South Dakota Medicaid's Pharmacy Director, testified:

Q. If you look at the second bullet point at the third sentence, it states, "The MAC price is then applied across all package sizes available, but is structured to insure that the profit to the pharmacist to dispense the generic product is higher than that associated with dispensing the brand product. This strategy provides pharmacists with an incentive to dispense generic products as well as to make recommendations to prescribers that they substitute brand products with generic therapy alternatives." As we established earlier, providing the provider with a profit was an important concern to South Dakota Medicaid, correct?

A. Yes.

(12/15/2008 Iversen Dep. at 99:15-100:8, Ex. 86.)

**F. Cross-Subsidization Of Inadequate Dispensing Fees**

44. In March 1993, the United States General Accounting Office prepared a Fact Sheet for Congressional Committees titled "Outpatient Drug Costs and Reimbursements for Selected Pharmacies in Illinois and Maryland." (Ex. 48 (Abbott Ex. 458).) The Fact Sheet contained the following statements:

- "Although total Medicaid reimbursements exceeded the pharmacies' total drug purchase costs for the drugs we reviewed, whether this represents unreasonable benefits for the pharmacies is not clear. Neither HCFA nor the states have determined what would be an appropriate margin between reimbursements and costs. Further, representatives of all nine pharmacies contended that because of insufficient dispensing fees they used the excess reimbursements to cover the drugs' dispensing costs. Only one of the nine pharmacies provided us an estimate of what it considered its average dispensing cost."
- "Because of fiscal constraints and competing budget priorities, HCFA officials noted that states considered the surveys too expensive. HCFA officials also noted that because states focused on reducing Medicaid costs, most state programs were

not willing to increase dispensing fees regardless of survey results. HCFA now allows each state to develop dispensing fees based on whatever methods or factors the state chooses to use.”

- “HCFA and state Medicaid officials agreed that pharmacies must often use excess Medicaid reimbursements to cover their dispensing costs. However, because the officials did not have current data on dispensing costs, they did not know what dispensing fees should be.”
- “Because of the issues raised by pharmacy representatives and Medicaid officials about the sufficiency of dispensing fees and the lack of current data concerning such fees, we do not know the extent to which reimbursements in excess of drug purchase costs represent a potential source for Medicaid savings in the two states studied. This will remain unclear until new data are collected on pharmacies’ actual dispensing costs. With this information, HCFA and the states could more realistically assess the potential to change reimbursement policies to achieve Medicaid savings. However, because of the 4-year moratorium on reducing reimbursement limits for outpatient prescription drugs and dispensing fees, HCFA headquarters and state Medicaid officials did not believe that surveys of dispensing costs or the evaluation of the appropriateness of state reimbursement policies would be appropriate at this time.”

45. Numerous state officials testified that they understood that their state payment methodologies for drugs methodologies resulted in the payment of a margin on ingredient cost which was used to offset perceived inadequacies in dispensing fees. For example:

(a) Cody Wiberg, former Pharmacy Program Manager, testified:

You have to look at both sides of the equation. You have to understand that we know, and this is a serious aspect of ain’t what paid -- “ain’t what’s paid.” We know AWP, “ain’t what’s paid.” But if we move towards more transparency and we get closer to reimbursing on the ingredient side at what providers actually pay, then we have to look at the dispensing fee side in the case of pharmacies, because we’ve always kept that below what we think the true cost of dispensing is to make up for the fact that there is some money being made on the ingredient side. So to the extent, again, that you start paying people a dispensing fee or a total reimbursement that does not even get back the cost of the drugs, plus the cost of labor and the computer systems and the lights and all that, you could have providers stop -- you know, start dropping out of Medicaid. And then this creates an access issue for very poor people. So -- yeah.

(3/14/2008 Wiberg Dep. at 171:21-172:18, Ex. 68.)

(b) Georgia Medicaid's Jerry Dubberly testified:

Q. (By Mr. Cole) Mr. Lavine asked you whether this practice of overcompensating on the ingredient cost and undercompensating on the dispensing cost was a secret practice, and you said, "No, not at all"; correct?

A. Correct.

Q. Georgia never did anything to conceal or hide this practice from CMS or HCFA; isn't that true?

MR. LAVINE: Object to form.

A. That is correct.

Q. (By Mr. Cole) And it was -- you told me that it was a -- a -- it was common among all of the states, at least the states that you interacted with, that they also followed a similar practice; correct?

MR. LAVINE: Object to form.

A. That is correct.

Q. (By Mr. Cole) And are you aware of any discussions among the state Medicaid programs to somehow conceal this practice from the federal Medicaid administrators at HCFA or CMS?

MR. LAVINE: Object to form.

A. No, I'm not.

Q. (By Mr. Cole) And given your experience in dealing with CMS and/or HCFA, do you think that CMS or HCFA was aware of this practice employed by not only Georgia but all of the other states that you dealt with?

MR. LAVINE: Object to form.

A. It calls for me to identify what they knew. I would think that they would know, but I don't have proof that they -- that was a -- something they were aware of.

Q. (By Mr. Cole) Let me put it this way: Would it surprise you for HCFA or CMS to say that it had no idea that states, including Georgia, were following this practice throughout the mid to late '90s?

MR. LAVINE: Object to form.

A. I would be highly surprised by that statement.

(12/15/2008 Dubberly Dep. at 384:10-386:7, Ex. 24)

\* \* \*

When you joined the Georgia Medicaid program, is it your understanding that that practice existed prior to your joining Georgia Medicaid?

A. Yes.

MR. LAVINE: Let me object to form.

Q. (By Mr. Cole) Is it your understanding that that practice, like some of the other topics we've talked about today, was a practice employed by other state Medicaid programs?

MR. LAVINE: Object to form.

A. Yes.

Q. (By Mr. Cole) In other words, Georgia wasn't the only state that was overcompensating providers on ingredient costs at the same time that they were undercompensating providers for their dispensing costs; correct?

MR. LAVINE: Object to form.

MR. SULLIVAN: Object to form.

A. Correct.

Q. (By Mr. Cole) Would you say that -- that most of the states, if not all of the states that you communicated with or have communicated with, given your position as the Georgia State Medicaid director -- that the majority of those states have employed a similar practice?

MR. LAVINE: Object to form. And I'd request you clarify whether this is a question you're asking as an official opinion of the Georgia department or his personal opinion you're seeking now.

MR. COLE: It's not a personal opinion. I'm asking -- I'm asking him as the representative of the Georgia Medicaid program if it's

his understanding, based on the communications that he has had with other states, that those other states had a similar practice of overcompensating providers on the ingredient cost while they undercompensated providers for their dispensing costs.

MR. SULLIVAN: Object to the form.

A. Yes, that is my understanding.

Q. (By Mr. Cole) Can you think of any state that did not have that practice?

MR. LAVINE: Object to form.

A. No.

(*Id.* at 332:5-334:6)

(c) Cynthia Denmark, Pharmacy Consultant in Delaware, testified that by no later than 1994 Delaware Medicaid officials believed that dispensing fees were not adequate to cover providers' costs for dispensing drugs, but did not see this as a problem because margins available to providers on the ingredient cost portion of drug reimbursements. (12/9/2008 Denmark Dep 179:17-181:15; 178:16-179:15, Ex. 22.) She further testified that Delaware Medicaid officials expressed concern that adjustments to the ingredient cost portion without considering changes to dispensing fees would adversely impact providers, because providers rely on margins from ingredient cost to make up for inadequate dispensing fees. (*Id.* at 181:16-183:1; *see also* Ex. 87 (Dey Ex. 609).) Ms. Denmark testified:

Q. Well, you indicated that the Delaware Medicaid Program wanted to increase the dispensing fee but because of budgetary reasons you were not able to do so; is that correct?

A. That's correct.

Q. Okay. So is it fair to say that because the Delaware Medicaid Program was unable to increase dispensing fees due to budgetary constraints that it was aware that providers relied upon a margin on the ingredient costs in some instances supplement for the inadequate dispensing fee?

A. Yes.

(2/10/2008 Denmark Dep. at 363:19-364:9, Ex. 88.). Ms. Denmark further testified that the issue of cross-subsidization was discussed within the Medicaid director community from since at least 1994. (*Id.* at 375:2-376:22.)

(d) North Carolina's Benny Ridout provide the following testimony:

Q. Was it your experience in the '80s that efforts to reduce estimated acquisition cost would result in pressures to increase dispensing fees?

MS. YAVELBERG: Objection, form.

MS. HAYES: Objection, form.

A. It was always the feeling, I think, of the pharmacy directors, those states that had a fee that was lower than what it cost to fill a prescription, that if they took anything off one side, they would have to put some on the other side to help so the pharmacists could make it. So if you got the actual acquisition cost on one side, and your fee didn't cover his cost to fill the prescription, you would have to raise that fee. In fact, I made that known to the OIG itself.

(12/5/08 Ridout Dep. at 142:3-19, Ex. 3.)

(e) Ron Gottrich, former Consultant Pharmacist with the Illinois Department of Public Aid, signed an affidavit that included the following statement:

It was also commonly discussed amongst those who administered Illinois Medicaid's pharmacy benefit that Illinois Medicaid's reimbursement formula for ingredient cost provided a margin relative to the cost of the drug, and that this margin served to both offset the inadequacy of the dispensing fee and compensate for the fact that Illinois Medicaid did not reimburse drug claims in a timely manner.

(Affidavit of Ron Gottrich, ¶ 5, Ex. 17.)

(f) Jerry Wells, former Pharmacy Program Manager in Florida, testified that Florida Medicaid realized its dispensing fees were inadequate and that, as a result, pharmacies would "have to have some margin or markup on the ingredient cost of the drug to offset that."

(8/15/2006 Wells Dep. at 103:5-17, Ex. 89.)

(g) Susan McCann, Pharmacist Consultant in Missouri, testified:

Q. . . . But is it your belief and your understanding as the pharmacist working at Missouri Medicaid that Missouri Medicaid knew it was paying a higher ingredient cost reimbursement than acquisition cost in order to compensate for a dispensing fee that was lower than what it otherwise thought it should have been?

(Objection)

A. That was my understanding.

(11/7/2007 McCann Dep. at 479:6-16, Ex. 90.)

(h) Tennessee's Leo Sullivan testified:

Q. And do you know in Tennessee, either before TennCare or after TennCare was paying a compounding fee for IV? Do you know if that was something that was being paid?

A. Ah, no. But there's, there's ways to pay it without, without having a separate -- you know, I noticed on here that one form is for payment, one form is for reimbursement of supplies, one form is for -- you know, they're, they're making a variety to submit multiple forms. And I wouldn't -- I can't tell you a specific product or specific time period, but one of my strategies was in issues like this, where compounding was involved, I didn't want to go down the road, at least in the early Nineties, of getting into paying for compounded prescriptions, because that can -- that could range from a sterile product all the way down to an ointment, okay? And, and our claims reimbursement system hadn't evolved to the current NCPDP sophistication of today. So it was very hard to put in a, a set compounding fee for what, what products. One may take a minute to make, one may take an hour and a half.

So getting back to, to the MAC issue, some, sometimes for certain products in this arena, you would take that into account for the MAC. For example, I might say, I'm not paying for the tape that you use to hold the IV needle into place. I'm not paying for the IV needle or the tube set. I'm not going to—I don't want bills for that. I know you've got to do it to administer this drug. So we're going to add on the cost of this drug X, because I know this, this and this always goes with it, and I know there is a fixed cost for that, but I don't want five bills. I want 10 different places. Bill me for the drug. And I'll make sure that the—whatever the MAC is

incorporates all your other costs. And you have to talk with providers and know what that is. I mean, you know.

Q. So, in short, you would use the payment for the drug itself to cross-subsidize other things that might need to be paid to fairly—

A. And that would include compounding.

Q. And it may include nursing services that were not included, things of that nature?

A. (Nodding yes.)

Q. Did anyone in the federal government ever tell you that you were not allowed to do that?

A. No.

(3/12/08 Sullivan Dep. at 152:16-155:04, Ex. 1.)

(i) In 2005, Louisiana increased its dispensing fee for 340B providers to \$8.10, higher than the dispensing fee paid to non-340B providers. Louisiana's M. J. Terrebonne testified regarding the impetus for this change:

Q. Do you recall if at some point Louisiana increased the dispensing fee paid to 340B hospitals?

A. We did.

Q. Do you recall the increase was roughly \$8.10?

A. Yes.

Q. And that is considerably higher than the dispensing fee paid to providers in the Medicaid program, correct?

MR. FAUCI: Object to the form.

THE WITNESS: Yes.

BY MR. TORBORG

Q. Why was there a difference between the two dispensing fees?

A. The secretary of the department felt that because the 340B providers were getting paid at actual acquisition cost, that they should be reimbursed a higher dispensing fee.

(3/31/08 Terrebonne Dep. at 212:6-213:2, Ex. 25.)

(j) Joseph Fine, Manager and, later, Director of Maryland's pharmacy

program testified:

Q. So Maryland knew that it was underpaying on the dispensing fee side?

MS. YAVELBERG: Objection, form.

A. We realized that -- it was an actuality. Our dispensing fee was approximately 3.70 at the time and it was a four-dollar-and-some cent statement from Myers & Stauffer. Okay? The federal government did not say we had to take what the survey amount was and use that as the dispensing fee. It was just to use it as a reference point to understand.

Q. And it knew, as you just testified, that it was allowing more than the actual acquisition cost on the ingredient side, correct?

MS. YAVELBERG: Objection, form.

A. Yes.

Q. It just didn't have a written policy that said that was happening?

MS. YAVELBERG: Objection, form.

A. The requirements of the federal government were not to pay pharmacies the actual acquisition cost. The requirements of the federal government was to give the best estimate of acquisition or estimate acquisition cost. There is no way that the State of Maryland could know what the actual cost the pharmacist paid for because it was understood by the State of Maryland that a volume purchase of a large active pharmacy compared to a small pharmacy was different. Therefore the discounting was different. And you had to look at the reasonableness of the estimated acquisition cost to allow for the differential. Otherwise it would have been impossible unless you audit each and every pharmacy to know what that individual price would be.

(2/09/08 Fine Dep. at 107:2-108:13, Ex. 91.)

(k) Frank Tetkoski, Manager of the Maryland Pharmacy Services Department,

testified:

Q. And what's being talked about here is a possibility of having to adjust the fee upwards if you were going to cut the ingredient cost, right?

MS. YAVELBERG: Objection, form.

A. Right. Adjustments have to be made as more and more it evolved where the prescription was a part of the ingredient cost and the fee would need to be -- if you just unilaterally cut the ingredient cost it would be hard to put through as well as just a flat cut which as we discussed before it would be very hard to even put through.

Q. What the state officials said is you can't just look at one side of the equation and adjust it without looking at other side, right?

MS. YAVELBERG: Objection, form.

A. Well, you have to look at everything. Yes.

(12/11/2008 Tetkoski Dep. at 190:16-191:9, Ex. 27.)

\* \* \*

Q. And then the next section, cost of dispensing survey, this is summarizing the survey that had been done by the University of Maryland School of Pharmacy, right?

A. Yeah. That's what it looks like. I didn't read this.

Q. And if you look at it it indicates that the average cost of dispensing per prescription is \$11.71 with a median cost of \$10.67, right?

A. That's what it's stating, yes.

Q. And then at the end of this paragraph it states "Again, this does not mean that pharmacists are not receiving adequate payment. One needs to examine the profit levels that are obtained with the acquisition costs." Do you see that?

A. Yes.

Q. What does that mean?

MS. YAVELBERG: Objection, form.

A. They may be making some money on the acquisitions costs and that needed to be figured in.

Q. And that's not something that just kind of came out of the sky in 2007; this has been something that Maryland has been looking at every since you've been in the policy department, isn't it?

MS. YAVELBERG: Objection, form.

A. When we look at reimbursement, again, we look at everything. You've got to figure everything in.

Q. And that's something you've been doing since you started in the policy department in 1994, right?

MS. YAVELBERG: Objection, form.

A. I guess my answer is we look at everything. Are you saying that -- I'm not specifically what you're directing that at, but --

Q. You consider the whole picture, the dispensing fee adequacy and the ingredient cost payments.

A. Yes, especially if you're trying to make any kind of adjustments.

(*Id.* at 201:7-203:2)

(l) James Kenyon, pharmacy supervisor in Michigan, testified:

Q . . . I'd like to look at the second sentence of that paragraph as well as the third, which reads: "The process of setting EAC screens is closely linked and balanced with setting dispensing fees. Payers are able to have low dispensing fee rates if they have high EAC screens."

Do you see that?

A. Yes.

Q. In your experience as a pharmacist and as working for Michigan Medicaid, do you have any reason to disagree with that statement?

MR. HENDERSON: Objection.

A. I would say I have no reason to, no.

\* \* \*

Q. So, is it fair to say that if drug costs were high enough, that could offset a dispensing fee that was too low?

MR. HENDERSON: Objection.

A. I would say yes.

(3/25/08 Kenyon Dep. at 19:11-20:14, Ex. 92; *see also* Ex. 93 (Abbott Ex. 657 (1994 document produced by Michigan: "EAC focuses on establishing screens at the lowest price that will maintain pharmacy participation regardless of the cost of the drug dispensed. The process of setting EAC screens is closely linked and balanced with setting dispensing fees. Payors are able to have low dispensing fee rates if they have high EAC screens."))

(m) Lise Farrand, Pharmaceutical Services Specialist in New Hampshire, testified:

Q. And also similar to the last first we have a section regarding reasonable dispensing fee. And New Hampshire Medicaid determined that the \$1.75 was a reasonable dispensing fee based upon what other third-party payors were paying, right?

A. That's what's listed in this document.

Q. It is not based on a study that was performed on dispensing costs, right?

A. That's not mentioned here.

Q. Rather, New Hampshire Medicaid was using a survey of the market of other third-party payors, right?

A. That is what's stated here.

Q. And the same is true for Estimated Acquisition Costs in that New Hampshire Medicaid reviewed what other third-party payors were applying as a discount to the AWP, right?

A. That's what's listed here.

Q. And it -- it states that -- well, that these discounts varied from 12 to 16 percent?

A. Yes.

Q. And so based upon what other third-party payors were doing, New Hampshire Medicaid determined that a 16 percent discount off of AWP was reasonable; is that right?

A. That is what is stated here.

Q. And it wasn't based on a survey of the acquisition costs of providers for purchasing drugs, right?

A. That's not mentioned here.

\* \* \*

Q. And today the dispensing fee in New Hampshire Medicaid is \$1.75, right?

A. Yes.

Q. And the dispensing fee was not set on dispensing costs but rather it was set based upon what other third-party payors were offering as their dispensing fees, right?

A. Yes.

Q. And New Hampshire Medicaid determined that when considering the dispensing fee, it considered also the ingredient portion of the formula, right?

MR. HENDERSON: Objection.

BY MR. KATZ:

Q. The EAC portion, right?

MR. HENDERSON: Objection.

BY MR. KATZ:

Q. I'll withdraw. Let me rephrase. In considering its reimbursement methodology, New Hampshire considered both the dispensing fee portion and the EAC or ingredient portion, right?

A. Yes.

Q. And it determined that overall, the reimbursement was adequate to the providers, right?

MR. HENDERSON: Objection.

THE WITNESS: From reading those letters, yes.

(10/28/08 Farrand Dep. at 117:18-119:4, 165:17-166:22, Ex. 94.)

(n) Gary Cheloha, Pharmacy Consultant in Nebraska, testified:

Q. And when Nebraska determines whether or not its reimbursement methodology is adequate to providers, it has to consider both the ingredient cost and the dispensing fee together; correct?

A. It considers them separately and together, yes.

Q. Okay. Could you explain what you mean by that?

A. Well, we calculate both, with pay based on the total of the two.

Q. Okay. So in order to find out how much a particular provider is being paid for a particular claim, you would have to add the ingredient cost and the dispensing fee?

A. That's correct.

(12/2/2008 Cheloha Dep. at 81:15-82:7, Ex. 28.)

\* \* \*

Q. . . . And then if you go down towards the end of that second paragraph, it states: Changing the EAC calculation without considering what acquisition and operating costs currently are today, and then determining what is fair and reasonable for all, is inappropriate.

A. Yes.

Q. Sitting here today, as a 30(b)(6), do you agree that it is necessary to consider both the acquisition and operating costs, which is the dispensing and ingredient portion, prior to making any changes in reimbursement?

A. Yes.

Q. And then if you turn to the second page, it has a similar statement. It says at the very top: We are asking that the proposed change to the calculation of the appropriate discount for the EAC of drugs and the dispensing fee for each pharmacy continue to be fact-based and that neither be changed without consideration for the total reimbursement allowed to those pharmacies that choose to

serve Medicaid clients. We request that HHS sponsor a new survey to determine the overall reimbursement and then implement its findings, as a number of other states have done. So once again, this sentence speaks to the need to consider both the discount of EAC and the dispensing fee?

A. Yes.

Q. And sitting here today, do you still believe that that's an important consideration to make?

A. Yes, I do.

(*Id.* at 186:3-187:14.)

(o) New Jersey's Ed Vaccaro testified that "it's entirely permissible for States to use the estimated acquisition cost, the ingredient cost portion to compensate pharmacists for inadequate dispensing fees." (12/3/2008 Vaccaro Dep. 352:09-353:11, Ex. 80.) Mr. Vaccaro also acknowledged that the state of New Jersey considered dispensing fees to be linked to ingredient costs such that "inevitably you would look at the two together."

Q. Okay. And given that this is a nationwide review comparing invoice price for drugs against AWP which -- do you agree that that is the ingredient cost portion of reimbursement?

A. Yes.

Q. Okay. Why would they discuss review of dispensing fees?

A. Dispensing fees are linked to ingredient costs.

Q. Can you elaborate further what you mean by link?

A. Well, the ingredient cost reflects the cost of purchasing a drug and a dispensing fee reflects the cost of dispensing that drug. Whether it's appropriate or not, it's what it is. It's a reflection of administrative costs for, or pharmacy costs, for dispensing the medication.

Q. Okay.

A. So inevitably you would look at the two together.

(*Id.* at 456:22-457:21.)

(p) Indiana's Marc Shirley testified:

Q. Do you think of those issues together as providing that total reimbursement must be adequate, or does reimbursement for each individual component need to be adequate?

MS. ST. PETER-GRIFFITH: Object to the form.

A. Once again, my sense on this is that ultimately your reimbursement for the service must be adequate to ensure participation by providers. And my sense is that providers probably don't much care one way or the other which side of the equation is which, as long as what they get from Medicaid is sufficient for them to render service.

So I think, you know, we act administratively in light of that. It makes sense to have a total reimbursement that is sufficient to maintain provider participation.

(12/2/2008 Shirley Dep. at 145:5-22, Ex. 18.)

46. CMS's Deidre Duzor, currently the Director of the Pharmacy Division for Medicaid, testified that she "was aware . . . that there was a spread in the ingredient cost and in some states that may have led to states not keeping their dispensing fees up to date in terms of cost to dispense because the overall reimbursement was generous." (2/27/08 Duzor Dep. at 405, Ex. 82.) Duzor acknowledged a CMS letter indicating that "Some public and private third party payors have purposely kept dispensing fee low precisely because there is a spread between AWP and AAC." (*Id.* at 424-27; Ex. 95 (Abbott Ex. 493).) Duzor explained that after passage of the Deficit Reduction Act, CMS acknowledged that states might need to review "their dispensing fees to assure that they are adequate to cover the cost of dispensing." (2/27/08 Duzor Dep. at 403-04, Ex. 82.) As Duzor testified that CMS understood that ingredient costs and dispensing fees were connected and that a decrease in ingredient cost meant that dispensing fees would likely increase:

Q. You, CMS, drew a connection between the two, decreasing the ingredient cost and increasing the dispensing fee, correct?

\* \* \*

A. Yes. I would say we drew a connection. We didn't say states should reconsider. We said something to the effect of states may want to look at or should review their dispensing fees in light of changes to ingredient cost reimbursement.

Q. And you expected that the dispensing fees would increase, correct?

A. Yes. We expected that should there be a need for change it would likely be an increase.

(*Id.* at 484:8-22.) Duzor testified that CMS "didn't believe it was a violation of the regulations, but we didn't think that it was a good thing" that providers were able to keep the difference between acquisition cost and what Medicaid was paying them to cover overhead and dispensing costs. (3/26/08 Duzor Dep. at 837:16-18, Ex. 54.)

47. Duzor further acknowledged that states paying very low dispensing fees would have to reassess their fees due to access concerns:

Q. Is it fair to say you can think of states where you would not feel comfortable that paying a true acquisition cost with no other changes to the reimbursement system would not be sufficient to ensure access?

\* \* \*

A. I don't know where the line would be drawn. But I think that there may be some states that were paying very low dispensing fees where that would not be adequate reimbursement for a pharmacy.

Q. And would you feel comfortable assuming that a change to paying actual acquisition cost would not have resulted in any change to dispensing fees at any of the state Medicaid programs?

\* \* \*

A. No. I think it may have resulted in a change in dispensing fees.

(2/27/08 Duzor Dep. at 527-28, Ex. 82.)

48. CMS's Larry Reed testified that CMS has had deliberations and come to a view as to the agency's position regarding cross-subsidization between ingredient costs and dispensing fees. However, Mr. Reed was unable to discuss neither the agency's position nor who from CMS was involved in the discussions regarding cross-subsidization due to the assertion of privilege by his counsel. Mr. Reed testified:

Q. Okay. And did you ultimately form a view as to the department's position on cross-subsidization between ingredient costs and the dispensing fee?

MS. OBEREMBT: Objection.

MR. DRAYCOTT: You're asking, did he form a view about the --

BY MR. MERKL:

Q. Well, did the department form a view?

MR. DRAYCOTT: About policy result, is that what you're asking?

BY MR. MERKL:

Q. No. I'm asking whether they actually came to a result.

A. Yes.

Q. Can you tell me what those deliberations were that led you to come to the result that you came to?

MS. OBEREMBT: Objection. I'm going to instruct him not to answer on the grounds of deliberative process.

BY MR. MERKL:

Q. And who was it who was involved in arriving at the view on the cross-subsidization issues?

MS. OBEREMBT: Objection. I'm going to instruct him not to answer because he hasn't said that anyone arrived at a view on cross- subsidization.

(10/2/08 Reed Dep. at 1194:11-1195:17, Ex. 55.)

49. In a 2002 report for California, Myers & Stauffer stated:

In fact, the acquisition cost study findings indicate that for a “typical” prescription, a pharmacy’s margin on ingredient reimbursement is approximately \$10. These margins on ingredient cost must be considered in tandem with an analysis of pharmacy dispensing cost and dispensing fee reimbursement in order to fully evaluate the issue of the adequacy of Medi-Cal pharmacy reimbursement.

(Ex. 96 (Myers & Stauffer, A Survey of Acquisition Costs in Pharmaceuticals in the State of California, June 2002).) Similarly, Myers & Stauffer stated in a contemporaneous report to California that “both dispensing and ingredient reimbursement rates should be considered in tandem.” (Ex. 97 (Abbott Schondelmeyer Ex. 4)).)

50. In response to questions by the Government, T. Allen Hansen, Myers & Stauffer’s 30(b)(6) witness, acknowledged that Myers & Stauffer cautioned against adjusting ingredient reimbursement while ignoring dispensing fee amounts.

Q. (By Mr. Gobena) So if I read these two recommendations together, in effect, Myers & Stauffer was recommending that the ingredient reimbursement in California in -- or in or around 2002 might be reduced -- should be reduced; is that correct?

Q. (By Mr. Gobena) That the discount rate should be increased, probably a better way of putting it?

A. I think the main theme of the sentences that you just read were that these changes should be considered together, that there were -- in essence, it’s a caution against adjusting one and ignoring the other for the reasons stated here.

(12/11/2008 Hansen Dep. at 562:9-563:2, Ex. 98, Ex. 99 (Abbott-Hansen 005).)

51. In 1999, under contract from the Louisiana Department of Health and Hospitals, Myers and Stauffer prepared a report analyzing the pharmacy dispensing costs and drug acquisition costs for providers serving Louisiana Medicaid beneficiaries. Myers and Stauffer found that “the costs to dispense I.V. prescriptions are not representative of the costs incurred by a general pharmacy” because “the activities and costs involved in filling I.V. prescriptions are

significantly different.” (Ex. 100 at 20-21 (Abbott Ex. 1051).) Myers and Stauffer concluded that “[a]lthough typical dispensing fees reimburse less than the dispensing costs of I.V. pharmacies, they are generally able to break even based on the margin allowed on the ingredient cost reimbursement.” (*Id.* at 21, n.6.)

52. In 2001, under contract from the Kentucky Department for Medicaid Services, Myers and Stauffer prepared a report on the cost of dispensing prescription medications to Kentucky Medicaid recipients. The report was titled “A Survey of Dispensing costs of Pharmaceuticals in the Commonwealth of Kentucky.” In its analysis of pharmacy dispensing costs, Myers and Stauffer found that “pharmacies that dispense I.V. prescriptions as a significant part of their business can have dispensing costs far in excess of those found in a traditional pharmacy.” (Ex. 101 at 20 (Excerpt of Abbott Hansen Ex. 6).) Pharmacists interviewed by Myers and Stauffer indicated that “the activities and costs involved in filling I.V. prescriptions are significantly different from the costs incurred by the typical retail (or long term care) pharmacy.” (*Id.* at 19.) In 2001, the Kentucky Department for Medicaid Services reimbursed providers who administered intravenous prescriptions based on a fixed dispensing fee plus ingredient reimbursement formula. Myers and Stauffer concluded that “[a]lthough dispensing costs at intravenous pharmacies is well in excess of the current dispensing fee, this reimbursement methodology has been accepted by these pharmacies because the margin on ingredient reimbursement has allowed pharmacies to offset any shortfall from the dispensing fee.” (*Id.* at 46.)

53. In 2002, under contract from the California Department of Health Services, Myers and Stauffer prepared a report titled “Study of Medi-Cal Pharmacy Reimbursement.” (Ex. 97 at (Abbott Schondelmeyer Ex. 4).) The report stated: “In every dispensing cost survey performed

by Myers and Stauffer in which data on the provision of intravenous services was collected, the provision of this service has been associated with higher dispensing costs. (*Id.* at 59.) Myers and Stauffer concluded that the average intravenous prescription “would yield a margin on ingredients of approximately \$42.” (*Id.* at 60.) The report stated: “This margin typically allows for adequate reimbursement of the pharmacy’s dispensing cost. So long as the ingredient reimbursement rate remains at AWP minus 5% or any other relatively ‘high’ level, the need for the Department to set a separate dispensing fee for intravenous drugs is somewhat mitigated by the margins realized on ingredient reimbursement.” (*Id.*)

54. An August 30, 2004 report prepared by Abt Associates, titled “Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices,” contained the following statement:

Most experts agree that AWP, or even the typical discounts to AWP, exceed actual acquisition costs for both pharmacies and physicians. This is particularly true for generic drugs. At the same time, these experts agree that Medicaid dispensing fees are low relative to actual dispensing costs. One panel member commented, ‘If it weren’t for the AWP spread, the pharmacies would be out of business.’ Payments based on the cost structure experienced by pharmacies may warrant payment of a reasonable and manageable spread (an amount paid above the actual acquisition cost).

(Ex. 59 at 7 (Abbott Ex. 381).)

55. OIG’s Ben Jackson, formerly the Acting Director, Operational and Program Reviews (Health Care Financing Audit Division), was involved in OIG’s two rounds of studies to determine the average discount off of AWP for brand and generic drugs. He testified that “some states could have said that the way they set their reimbursement rates for drugs could also have been tied in to how they did their dispensing fees,” and that the two components “were together. [The states] looked at them as a whole and not separate.” (12/12/2008 Jackson Dep. at 215:18-216:2, Ex. 37.)

56. After Congress passed the Deficit Reduction Act of 2005, which proposed to decrease ingredient cost payments for many multiple-source drugs by calculating federal upper limits based on 250% of AMP, numerous states proposed or passed legislation to increase dispensing fees to offset the decrease in ingredient cost payment. (Ex. 102 (Abbott Ex. 488).) Deirdre Duzor, the Director of the CMS Pharmacy Division for Medicaid, testified related to this issue:

Q. Do you have an understanding of what Louisiana's rationale was for proposing an increase to its dispensing fees?

A. I believe part of their rationale was to offset the reduction expected in the FUL reimbursement in the reimbursement for generic drugs because of the new federal upper limit.

Q. Have you heard that other states are contemplating an increase in dispensing fees if there would be a decrease in the ingredient base reimbursement based upon the change in the FUL calculation?

A. Yes, I have.

(2/27/2008 Duzor Dep. at 279:18-280:8, Ex. 82.)

57. The Congressional Budget Office, Congress, and CMS officials all recognized that decreases in ingredient reimbursement contemplated by the Deficit Reduction Act would necessitate increases in dispensing fees. (Ex. 103 (Abbott Ex. 520).)

- In a May 12, 2006 letter to HHS Secretary Michael Leavitt, Charles Grassley, Senate Finance Chair, stated: "CMS should make clear to states that they should reconsider their dispensing fees paid to pharmacies under Medicaid, particularly for generic drugs."
- On November 3, 2005, Senator Grassley stated during debate on the Deficit Reduction Act of 2005: "States will need to review and increase the fees that they pay pharmacies for dispensing Medicaid prescriptions. The overall assumption under the bill is that states will increase their fees to account for the fact that states would probably be paying pharmacists a lower amount for the drug product that more accurately reflects the cost of the drug being dispensed."
- In its January 27, 2005 report on the Deficit Reduction Act of 2005, the CBO stated: "The Congressional Budget Office's (CBO's) projected savings "reflect

CSO's expectation that states would raise dispensing fees to mitigate the effects of the revised payment limit on pharmacies and preserve the widespread participation of pharmacies in Medicaid."

- In a November 15, 2006 meeting of the National Association of State Medicaid Directors Conference, Duzor stated: "States should be reviewing the adequacy of Medicaid pharmacy reimbursement."

(*Id.*)

**G. Payment Rates Were Negotiated And/Or Set By State Legislatures**

58. Numerous state officials explained that they arrived at their drug payment rates through a process of negotiation with legislators, Governors, Medicaid officials, and pharmacy providers. For example:

(a) When CMS asked in 2001 how Illinois came to its reimbursement rate, Illinois told CMS that "[o]ur drug cost methodology was derived via two step approach which included 1) a thorough review of what other State's were doing and selecting the percentage off of AWP that was reasonable and 2) conducting negotiations with the Pharmacy Industry." (Ex. 104 (Abbott Ex. 769).)

(b) Idaho advised CMS that "[r]epresentatives from the state pharmacy association, hospital association, and retailer's association met with the Department numerous times to negotiate reimbursement rates for pharmacies." (Ex. 105 (Abbott Ex. 491).)

(c) New Jersey's Ed Vaccaro testified:

Q. During your time at Medicaid -- I'm sorry. Let me clarify it. During the 1990's, was that a concern to not incur the wrath of National Pharmacy Associations when you were developing reimbursement methodology?

A. I think there was a strategy implemented by the agency starting in the early 90's and forward that brought interested parties, advocates to the table before they made decisions that impacted, for example, reimbursement.

Q. When you say agency, which --

A. Advocates. We're talking about whether it be beneficiary advocacy groups or if we were going to somehow impose changes on eligibility. In the case of pharmacy we brought the associations to the table, including Pharma, when it was appropriate to do so, for the purpose of taking in their recommendations regarding reimbursement. For example, if we were proposing a certain level of reimbursement that we knew would be antagonistic we would ask them for their own proposals as alternatives to a change in reimbursement if indeed a goal was to save dollars. That kind of thing.

So what I think you're looking at here is in the 90's our efforts to try and, you know, reduce the rhetoric, if you will, from the various professional organizations, state or national, they would bring their national advocates in with them. Okay. And to try and work things out with interested parties ahead of time before we put something in place.

(12/2/2008 Vaccaro Dep. at 239:9-240:20, Ex. 30.)

\* \* \*

Q. You testified earlier that in certain instances when New Jersey Medicaid had proposed reimbursement policies there were a variety of interests involved that were not affiliated with New Jersey Medicaid; is that correct?

A. That's correct.

Q. One of those interest groups were pharmacy associations; is that correct?

A. Yes.

Q. Would you agree that pharmacies had an interest in keeping reimbursement high?

A. Yes.

Q. And would you also agree that pharmacy advocacy groups place pressure on New Jersey Medicaid to keep reimbursement high?

A. Yes.

Q. You testified earlier also about the New Jersey Pharmaceutical Association; is that correct?

A. Yes.

Q. What types of, I'm sorry. What kinds of pharmacies do they represent?

A. Non chain pharmacies.

Q. Independent pharmacies; is that correct?

A. Yes.

Q. And do they represent only pharmacies located in New Jersey?

A. Yes.

Q. Do you know how many members are in that association?

A. I do not.

Q. Would it be in the hundreds?

A. Yes.

Q. Thousands?

A. Likely the thousands.

(*Id.* at 263:15-265:8.)

\* \* \*

Q. So it's more than 50 percent of New Jersey pharmacies, independent, sorry, pharmacies?

A. It's not likely more than 50 percent because there are, I think there are five professional pharmacy organizations in the state. They sort of share who's going to be a member of what. Some are members of two associations. There's actually an association of chain drug stores, just for chain stores. That's only chain stores.

Then you have New Jersey Pharmacists Association, Garden State Pharmacy Owners, Independent Pharmacy Alliance. Those three share membership with, some pharmacies may be in some associations and not in others, so it might be in the hundreds, the high hundreds, maybe seven or eight hundred members are part of the Pharmacists Association. Same number might be in the Garden State Pharmacy Owners but there might be a duplicate membership.

Q. Okay. So you mentioned five pharmacy groups. Did they exist in the 1990's?

A. Yes.

Q. Under those names?

A. Yes.

Q. Early 1990's?

A. Definitely in mid 1990's.

Q. In 1990's?

A. I think they became stronger in the early 90's because of our transition between fiscal agents and the impact it had on the pharmacy community.

Q. I see. Were they present during any of the reimbursement proposals during the 1990, mid 1990's?

A. They would have been invited to sit with the division to talk about prospective proposals for the budget year coming up. Whether or not they actually were, you know, listened to or worked with is a different story but at least the invitation went out to have them talk to us so we would try to minimize any kind of negative impact to a policy change on them.

Q. So did New Jersey Medicaid, in fact, meet with any of these associations --

A. I would say yes.

Q. -- during the mid 1990's?

A. Yes, we would.

Q. Do you recall which ones specifically?

A. I think we met with them all as a group. We actually got to the point of inviting them all down together. Representatives from each organization would come down and sit and talk to us.

(*Id.* at 265:9-267:22.)

\* \* \*

Q. Okay. Now, if you just go -- skip a paragraph and go to the paragraph that starts with: While -- while I believe, the second sentence he says, "I expect strong resistance from the provider community and a long and arduous negotiation." What does he mean by negotiation.

A. As I indicated in testimony yesterday, we often, even back in the '80s, I would imagine, we often sat across the table from professional organizations in the State, professional pharmacy organizations, to discuss our intentions regarding changes in -- typically reimbursement, and this is an example of that.

Q. Okay. And this is prior to Medicaid agencies submitting a State plan for approval?

A. Yes.

(12/3/2008 Vaccaro Dep. at 414:9-415:3, Ex. 80.)

(d) Colorado's Allen Chapman testified:

Q. And when Colorado set its reimbursement rate for prescription drugs, it had to set its reimbursement rate high enough to ensure that enough providers participated, right?

MR. ANDERSON: Objection, form

A: I'm sure that was one of the criteria. It wasn't the only criteria.

Q. Okay. What were some of the other criteria?

A: Studies that were done within the state, negotiation.

Q. And when you say studies, you're referring to studies regarding dispensing costs and acquisition costs?

A: Correct.

Q. And when you say negotiations, you're referring to negotiations with the pharmacy community, right?

MR. ANDERSON: Objection, form.

A: And other parties.

(12/15/2008 Chapman Dep. at 46:1-21, Ex. 11.)

(e) When asked how Delaware arrived at its reimbursement rate, Cynthia Denmark testified that Delaware Medicaid “worked with the provider community leaders to establish a rate that would [] permit [pharmacies] to continue being [Delaware Medicaid] providers.” (12/9/2008 Denmark Dep at 150:17-153:17, Ex. 22.)

(f) North Dakota considered adequacy of reimbursement levels when making overall changes to its reimbursement formula and considered its reimbursement levels to be adequate as long as it paid the same amounts as Blue Cross Blue Shield North Dakota.

Q. And did North Dakota consider the adequacy of reimbursement when it made those changes?

A. The changes that we made with the, for instance, the MAC pricing, we used the private sector MAC pricing. So any evaluation of adequacy was solely based on the fact that this is what they get paid by Blue Cross Blue Shield of North Dakota which accounts for 80 percent of the claims in the state. Therefore, we assume it must be accurate. Or adequate. Because we were then paying the exact rates as Blue Cross Blue Shield of North Dakota.

(2/12/2008 Joyce Dep. at 74:3-15, Ex. 19.)

(g) New Hampshire’s decision to begin discounting AWP by 12% in 1996 was reached after negotiations with pharmacies. (10/28/2008 Farrand Dep at 96:15:97-21, Ex. 94, 10/29/2008 Clifford Dep at 53:3-54:12, 55:13-56:12, 174:1-7, Ex. 106.)

(h) Rather than try to accurately estimate acquisition costs when it changed its reimbursement rate in 2001, Wisconsin relied on information from several sources, including pharmacy representatives and reimbursement rates set by other states, to determine Wisconsin Medicaid’s reimbursement formula. (Ex. 107 (Abbott Ex. 773); Ex. 108 (Abbott Ex. 1073).)

(i) Arkansas’s reimbursement methodology was affected by political considerations and “provider relations issues,” such as opposition from industry lobbying and

concerns by those in the pharmaceutical industry. (12/10/2008 Bridges Dep at 300:15-301:6, Ex. 109; 12/11/2008 Bridges Dep at 375:13-21, Ex. 10.)

(j) Alaska's decisions regarding reimbursement rates were also influenced by the political process and the state had to account for "political realities," and "whether or not [the state] has the political capital to force through a change." (8/19/2008 Campana Dep at 161:18-162:8, 163:14-164:4, Ex. 8.)

(k) California's reimbursement policy was substantially affected by political negotiations, provider concerns, and lobbying by pharmacy groups. (12/3/08 Gorospe Dep. at 47:18-49:14, Ex. 110.) California's Stanley Rosenstein testified:

Q: Earlier it [referring to Rosenstein Exhibit 12] says – the May Revision had suggested cuts in the ingredient cost rate to AWP-40 percent for generic drugs based on the findings of the Myers and Stauffer report, correct?

A: That's correct, uh-huh.

Q: That would have been a closer approximation to providers' actual acquisition; correct?

A: That's correct.

Q: But the – you characterized the Department's position with respect to Section 73 as a "compromise."

A: That is correct. Our – our initial position was – what was proposed in the Governor's May Revision, that's where we wanted to be.

It – you know, it's a legislative process, and you have to work with the Legislature and advocates and come to a compromise on occasions.

(5/19/2009 Rosenstein Dep. at 176:6-177:4, Ex. 111.)

\* \* \*

Q: Would you turn back to the third paragraph there on page 93. The final sentence says, "In recognition of CPhA's contentions, the

DHS modified the original May Revision proposal to AWP-10 percent for all drugs,” correct?

A: That’s right.

Q: Doesn’t that suggest that the Department itself did compromise in its original proposal?

A: Yeah. As I said, it was a compromise. You know, we negotiated this between the legislative staff and the stakeholders.

(*Id.* at 178:7-20 (objection omitted)) California’s Vic Walker testified as follows:

Q: Okay. The next section states [referring to Walker Exhibit 8] “Legislative History. This identical proposal has been made almost every year since the early 1990s, but has been fought to a standstill in every instance by the effective lobbying efforts of the pharmacy provider organizations and beneficiary advocacy organizations.” Did I read that correctly?

A: Yes.

Q: And was that your understanding of – the legislative history of this proposed change to reimbursement when this document was prepared?

A: Yes

(5/21/2009 Walker Dep. at 119:10-22, Ex. 112.)

(l) Florida’s reimbursement methodology was also influenced by pharmacy lobbying groups, such as the Florida Pharmacy Association. (12/15/2004 Wells Dep at 124:7-125:3, Ex. 12.)

(m) Georgia’s Jerry Dubberly admitted that Georgia’s reimbursement formula was at least in part shaped by politics:

Q. Is it fair to say that the reimbursement formula that Georgia Medicaid applies has been shaped at least in part by political considerations?

MR. LAVINE: Object to form.

A. Yes.

(12/15/08 Dubberly Dep. at 257:3-8, Ex. 24.)

(n) James Kenyon explained that providers had to be consulted before

Michigan Medicaid could make any changes in reimbursement:

Q. Okay. Do you know why there was a requirement that the provider community be consulted with?

A. Any changes in reimbursement has to go out for consultation.

(3/25/2008 Kenyon Dep. at 27:14-18, Ex. 92.)

(o) When setting reimbursement rates for prescription drugs, Oklahoma

Medicaid consulted with pharmacy associations. Oklahoma's Nancy Nesser testified:

Q. Does Oklahoma consult with any pharmacy associations in general when setting policies or rates for reimbursement of prescription drugs?

A. Yes.

Q. Which pharmacy associations?

A. We consult with the Oklahoma Pharmacists Association, and there's another group called Pharmacy Providers of Oklahoma.

(12/12/2008 Nesser Dep. at 225:9-16, Ex. 7.)

(p) Larry Iversen testified that provider's influence on South Dakota Medicaid

influences its reimbursement methodology:

Q. If you look at the last sentence of this paragraph, it states, "Since Medicaid programs are operated in a political environment in which providers are stakeholders, the methodology employed in constructing the SMAC list must be sound in order to validate the appropriateness of the program as well as respond to inquiries from providers." Do you agree that the state Medicaid program is operated in a political environment?

MS. ACTON: Objection, form.

A. Yes.

Q. (BY MS. KHANDHAR) And how would you describe that political environment? What makes it political?

A. Because the state legislature approves or disapproves of the funding of the Medicaid program.

\* \* \*

Q. They would be stakeholders in that way because the reimbursement would be important to them in terms of how much money they make and whether they make a profit, correct?

A. Yes.

Q. And providers are important to the overall South Dakota Medicaid because it would be important to South Dakota Medicaid to have enough providers in order to insure access to care, as we established earlier, correct?

A. Yes.

Q. And did the fact that the programs operated in a political environment affect the reimbursement methodologies that were adopted?

MS. ACTON: Objection to form.

A. Probably.

Q. (BY MS. KHANDHAR) And in what way do you think?

A. Again, because the legislature approves of the budget for the Medicaid program, then that relates to the reimbursement methodologies.

Q. Since the providers are stakeholders in the Medicaid program, the Medicaid program would want to keep those providers happy in order to insure that they were enrolled, correct?

MS. ACTON: Objection, form.

A. Yes.

(12/15/2008 Iversen Dep. at 91:3-93:19, Ex. 86; *see also* Ex. 113 (Dey Ex. 911).)

(q) When asked to explain in 2003 how its reimbursement rate of AWP – 11% plus a dispensing fee of \$3.91 was its “best estimate,” Oregon provided the following statement to CMS: “The October 4, 2002 legislative Emergency Board directed the Department to increase

the rates to institutional pharmacies to AWP - 11% plus dispensing fee of \$3.91. Oregon submitted a SPA exactly as requested by this legislative body, and the documentation was previously submitted with SPA 02-06.” (Ex. 114 (HHC020-0382).)

#### **H. Attempts To Reduce Payment Rates To Acquisition Cost Were Rejected**

59. Evidence demonstrates that efforts to state Medicaid reduce payment rates were curbed or defeated by political pressure from pharmacist and provider groups, or because state decision-makers did not believe reductions in ingredient cost were appropriate or warranted. For example:

(a) On August 30-31, 1994, officials from CMS, OIG, and various state Medicaid programs met to discuss OIG’s nationwide review of the difference between the invoice price for drugs and AWP, for pharmacy providers. (Ex. 115 (Abbott Ex. 581).) OIG’s “Record of Discussion” of that meeting includes the following statement:

The state officials expressed concern that our review was limited to one aspect of pharmacy reimbursement. They said that any effort to lower the reimbursement for acquisition cost should also include some review of dispensing fees. They stated that we should include a fifth category of pharmacies to include non- traditional retail pharmacies such as hospitals, home IV, nursing homes, physicians etc ... The state officials believed that these pharmacies purchased at substantially bigger discounts than traditional retail pharmacies. They also stated that we should request the largest invoice from each different type of supplier rather than just the largest invoice.

(*Id.*)

(b) On September 27-28, 1995, officials from CMS, OIG, and various state Medicaid programs met to discuss the results of OIG’s nationwide review of the difference between the invoice price for drugs and AWP, for pharmacy providers. (Ex. 116 (Abbott Ex. 582).) OIG’s “Record of Discussion” of that meeting includes the following statement:

We presented the results of our AWP review. The State officials believed that our results were in line with what they had

anticipated and confirmed that current State practices of reimbursing ingredient cost below AWP was appropriate.

We reviewed a draft copy of a State report. The State officials believed that the report should include the following disclaimer:

‘Our review was limited to ingredient acquisition costs and did not address other areas such as: the effect of Medicaid business as a contribution to other store sales; the cost to provide professional services other than dispensing a prescription such as therapeutic interventions, patient education, physician consultation; and the cost of dispensing which includes costs for computers, multi ....part labels, containers, technical staff, transaction fees, Medicaid specific administrative costs, and general overhead. We also did not take into consideration the effect of Federal upper limits amounts on generic drug reimbursements or usual and customary charge limitations.’

The State officials were concerned that without the above disclaimer, that uninformed State officials might overreact to our report and adjust pharmacy reimbursement without considering the other aspects of reimbursement.

The State officials also expressed a desire re to obtain a copy of the data reviewed for their respective States so that they could analyze. Ben Jackson said that we could provide this data.

(*Id.*)

(c) In 1997, the OIG issued a report to Maryland stating that Maryland pharmacists were purchasing generics at an average 41.9% discount below AWP. (Ex. 117 (Abbott Ex. 1064).) Maryland’s Joseph Fine testified regarding the report:

Q. I’ll hand you what we’ve marked previously as Abbott Exhibit 1064 this is a report dated February 1997 titled “Review of pharmacy acquisition costs for drugs reimbursed under the Medicaid prescription drug program of the Maryland Department of Health and Mental Hygiene.” It also includes a cover letter. Have you seen this document before?

A. Yes.

Q. Did you receive a copy of it on or around the time it was prepared by OIG?

A. Yes.

Q. Do you recall any discussions within the department about this report?

A. The discussion was there was no conclusion that we didn't already know. That was the internal discussion on this.

Q. Did you play any part in preparing Maryland's response to the report that's the last two pages of the exhibit?

A. Yes.

Q. What was your involvement?

A. I was more interested in the wholesale acquisition cost methodology as a stabilizer for inconsistent average wholesale prices. And that was my part in this.

Q. Go to the Bates page ending 630, the section for generic drugs. At the top it states "We estimate that invoice prices for generic drugs were discounted 41.9 percent below AWP," correct? Is that right?

A. That's what it says here.

(12/09/08 Fine Dep. at 238:5-239:13, Ex. 91.) An internal Maryland document discussing OIG's findings, dated April 16, 1997, contained the following statement:

The Maryland reimbursement rate could be reduced by shaving a few more points off the AWP price. One good reason for this would be to prevent the reimbursement for brands drugs being more attractive than for generics. . . . But the Program did not change from AWP-10% in the current regulation amendments due to the possibility of strong objections from pharmacy providers.

(Ex. 118 (Abbott MD Ex. 30).)

(d) In 1996, Virginia Medicaid received and responded to OIG's 1996 survey of pharmacy acquisition cost for drugs reimbursed under the Virginia Medicaid program. (Ex. 119 (Roxane VA Ex. 5).) The report found that in Virginia the "overall estimate of the extent that AWP exceeded pharmacy purchase invoice prices was 17.2 percent for brand name drugs and 45.1 percent for generic drugs." (*Id.*) In its response to a draft of the report, Virginia stated:

DMAS appreciates the recommendation that Virginia Medicaid consider the results of this review as factor in any future changes to pharmacy reimbursement for Medicaid specific drugs in the state program. As stated, Medicaid reimbursement rates to pharmacy providers for covered outpatient prescription drugs consist of two components which are an amount representing the drug ingredient cost, the acquisition cost, and an amount representing the professional or dispensing fee. Normally, the reimbursement cost is based on the lower of EAC, estimated acquisition cost, usual and customary, or FUL, Federal Upper Limit and Maximum Allowable Costs. As stated in the draft of these reviews, the acquisition cost is just one factor involved in pharmacy reimbursement policy or methodology and with any change, consideration should be given to other factors such as the following:

- Impact on recipient access to service
- Present rebate allowances from pharmaceutical manufacturers to both federal and state programs
- Provider specialty care or level of care such as Home Health providers, Coordination of monitoring for recipients with compliance needs
- Overhead costs for dispensing functions and record keeping

This does not necessarily cover inclusively those factors that are involved in assuring that the Medicaid recipient receives the most efficient and cost effective health care available, but does emphasize that when one aspect of the equation is affected, all possible consequences should be considered.

(*Id.*). Virginia continued to use an EAC of AWP – 9% for both generic and branded drugs until 2002, when it was changed to AWP – 10.25%. Virginia decided against changing its definition of EAC at that time it received the 1996 OIG Virginia report. Virginia’s Bryan Tomlinson testified:

Q. In the conclusions and recommendations of the OIG, in this report, covered the acquisition costs to pharmacies in Virginia, it is recommending the following: “We believe that the difference between AWP and pharmacy acquisition costs, as determined by our review, is significant enough to warrant consideration by the state in any evaluation of the drug program. Therefore, we recommend that the state agency consider the results of this review

in determining any future changes to pharmacy reimbursement for Medicaid drugs.” Correct[?]

A. Yes.

Q. And you understand that the OIG is recommending to DMAS that it should take under advisement the findings of this report?

A. Yes.

Q. And those findings were that branded drugs were typically acquired at discounts of AWP minus 17.2 percent in Virginia, and that generic drugs were acquired, on average, at 45 percent discounts off of AWP, correct?

A. That was their findings, yes.

Q. And DMAS’s response to these findings was not to change its reimbursement methodology, it’s determination of estimated acquisition cost, correct?

A. There was no change during that time period.

(11/3/2008 Tomlinson Dep. at 251:16-253:1, Ex. 120.)

(e) In 1996, Montana Medicaid received and responded to OIG’s 1996 survey of pharmacy acquisition cost for drugs reimbursed under the Montana Medicaid program. (Ex. 121 (Abbott Ex. 327).) The report found that in Montana the “overall estimate of the extent that AWP exceeded pharmacy purchase invoice prices was 16.2 percent for brand name drugs and 48.5 percent for generic drugs.” (*Id.*) In its response to a draft of the report, Montana stated:

It is important to note that the study did not investigate the payment of these services by Medicaid, only the cost of acquisition of the drug by the providers. We believe all states involved are concerned that if these numbers are directly compared to the discounted AWP method of Medicaid Pharmacy pricing, confusion and questions will arise. The two major factors that must also be considered if this comparison is done relate to the dispensing fee

portion of the payment formula and the effect of Federal upper limit (FUL) pricing for generic drugs. No work was performed by the OIG to determine how total reimbursement for pharmacy services relates to the cost of providing the service.

It is expected that when these results are published that the immediately concerns will be raised that pharmacy providers are being reimbursed more than the acquisition cost of the products and that changes should be made to the pricing formula to increase the discount on AWP. In order to address these concerns, states must do additional work to determine whether the cost to dispense is being accurately reimbursed and what effect the FUL pricing has on the discount for generic. In Montana we currently believe that the dispensing fee is below the cost to dispense because of the capon dispensing fees that is currently in place and has been for many years.

(*Id.*) Montana did not change its EAC formula (AWP minus 10%) in response to OIG's report.

(f) In 1996, Missouri Medicaid received and responded to a draft of OIG's 1996 survey of pharmacy acquisition cost for drugs reimbursed under the Missouri Medicaid program. (Ex. 122 (Roxanne Ex. 144).) The report found that in Missouri the "overall estimate of the extent that AWP exceeded pharmacy purchase invoice prices was 18.5 percent for brand name drugs and 46.4 percent for generic drugs." (*Id.*) In its response to a draft of the report, Missouri stated:

It was recognized in the 1990-91 study, as in your report, that ingredient cost is only one component to be considered in determining an appropriate pharmacy reimbursement level. Please note, that in September, 1991, the ingredient cost portion of the methodology was reduced to the amount reflected in the study; the standard professional dispensing fee was not raised to the recommended rate of \$6.56 for independent pharmacies and \$6.20 for chain pharmacies. The current standard dispensing fee of \$4.09 remains below the established cost to dispense, as identified in the 1990-91 study (\$5.69 for independent and \$5.45 for chain pharmacies).

One of the goals of DSS is to optimize the access to and the quality of health care services to the department's clients, partners and stakeholders. Toward that end, we must identify and take into consideration as many essential variables as possible in order to develop reimbursement policies that are adequate for providers and fair to Missouri taxpayers.

(*Id.*) Missouri did not change its EAC formula (AWP minus 10.43%) in response to OIG's report.

(g) In 1996, Florida Medicaid received and responded to OIG's 1996 survey of pharmacy acquisition cost for drugs reimbursed under the Florida Medicaid program. (Ex. 51 (Abbott Ex. 84).) The report found that in Montana the "overall estimate of the extent that AWP exceeded pharmacy purchase invoice prices was 20.2 percent for brand name drugs and 41.5 percent for generic drugs." (*Id.*) In its response to a draft of the report, Florida stated:

Comparing acquisition costs for Florida pharmacies to AWP, as an academic exercise, proves that pharmacies, like almost all retail businesses, purchase goods at some discount below suggested list prices, but does not provide an indication of need to change current reimbursement policy. . . .

We can conclude from the survey results that some manufacturers do not correctly report promotional prices for competitive products and the reported EAC price may be inflated by as much as a factor often times actual cost. most of these cases, Florida imposes the federal upper limit price which also does not fully capture all available discounts and pharmacies may still have significant markups. In most cases, the products are multi-source. Restricting reimbursement to actual cost might have the unintended effect of discouraging purchase of promotional products and eventually shifting the market to single-source products which are universally much more costly. The average multi-source prescription costs Medicaid less than \$11 and the average single -source product averages over \$45.

(*Id.*) Florida did not change its EAC formula in response to OIG's report.

(h) In 1996, California Medicaid received and responded to a draft of OIG's 1996 survey of pharmacy acquisition cost for drugs reimbursed under the Missouri Medicaid program. (Ex. 123 (Abbott Ex. 325).) The report found that in California the "overall estimate of the extent that AWP exceeded pharmacy purchase invoice prices was 17.5 percent for brand name drugs and 41.4 percent for generic drugs." (*Id.*) In its response to a draft of the report, California stated:

We received your correspondence and the copy of the draft report on February 28, and have reviewed the results of the audit contained in the draft report. The draft report data indicates that a reduction in our drug ingredient cost reimbursement would be appropriate at this time. DHS intends to use these results, when published in the final report, to support a provision of our Governor's budget proposal to decrease drug ingredient reimbursement. The audit results will, hopefully, substantiate DHS' position that current drug ingredient cost reimbursement by the Medi-Cal program does not reflect actual purchasing activity of California pharmacies.

(*Id.*) California did not change its EAC formula (AWP minus 5%) in response to OIG's report.

(i) In addition to Maryland, Virginia, Montana, Missouri, Florida, and California, OIG issued reports in 1996 and 1997 to Delaware, District of Columbia, Nebraska, New Jersey, and North Carolina. With the exception of New Jersey, which reduced its reimbursement rate from AWP minus 2 to 8% to AWP minus 10%, none of these five states changed their EAC formulas in response to OIG's report. In August of 1997, OIG issued a report to all states showing the result of their 11-state survey that the average discount off of AWP for generic drugs was 42.5%. (Ex. 50 (Abbott Ex. 158).) In that report, OIG also informed the states of the article published by Forbes on June 10, 1996 titled "Hooked on Drugs," which found that the true cost was 10 to 20 percent below AWP for brand name drugs and 60 to 85 percent below AWP for generic drugs. (*Id.*)

(j) New Jersey's Ed Vaccaro testified:

Q. And were changes in the reimbursement rate for pharmacies contested?

A. Yes.

Q. And by whom?

A. The pharmaceutical associations typically contested it.

(12/2/2008 Vaccaro Dep. at 69:7-12, Ex. 30.)

\* \* \*

Q. And why didn't the general assembly adopt all of the cost contain measures proposed by DMAHS?

A. We work in a very strong political environment in New Jersey that's sensitive to the wants and needs of constituents, typically, demonstrated to the legislature through lobbying efforts. Inevitably, these efforts would result in certain initiatives that we would propose being turned down.

Q. And were, I think you mentioned pharmacy associations?

A. Yes.

Q. What are the names of some of those pharmacy associations?

A. Garden State Pharmacy Owners. New Jersey Pharmacists Association. Pharma. Pharmaceutical Manufacturers Association. IPA, Independent Pharmacy Association. 1, 2, 3, 4. Of course, the Association of Long Term Care Pharmacy Providers. That's pretty well it.

(*Id.* at 82:18-83:16.)

\* \* \*

Q. . . . Knowing that there was a approximate 40 percent discount between -- off of AWP, New Jersey decided, nonetheless, to reimburse at AWP minus 10 percent.

Q. Correct?

A. Correct.

Q. Okay. Why didn't New Jersey decide to reimburse at AWP minus 20 percent which was the approximate discount off of generics that are dispensed in New Jersey Med -- in New Jersey?

MS. YAVELBERG: I think you meant brands.

MR. KIM: Oh, I'm sorry. Did I say generic?

MS. YAVELBERG: You said generic.

BY MR. KIM: Okay. Correction. I meant brands.

A. Okay. The decision is -- is likely the result of the outcome of the open budget process where we invited providers to the table to

discuss changes proposed for the budget year and they may have proposed something greater than the 10 percent and end up coming down to 10 percent because of the need to satisfy the political process effectively.

(12/3/2008 Vaccaro Dep. at 484:04-485:14, Ex. 80.)

\* \* \*

Q. Okay. Did New Jersey at this time consider having a tiered reimbursement?

Let me explain what -- what I mean by that, is having a reimbursement rate for generics and a reimbursement rate for brands with different percentage discounts.

A. In the mid '90s?

Q. In 1995 or '96 when the AWP minus 10 percent proposal was being considered.

A. It might have been proposed, but never got through the first step of the open budget process. It might have been an idea that the Division supported, but never moved any further 'cause I know later than that time, that's why I asked the year, it was proposed that we split again. It never -- it never won support, sufficient support to get adopted.

(*Id.* at 486:16-487:10.)

\* \* \*

Q. Okay. Sir, you mentioned that there was once a proposal that did not go through eventually, but it was a proposal that separated the -- or had diff -- different discounts off of AWP for generics and -- and brands?

A. Correct.

Q. Okay. And you also mentioned that this proposal did not go through because of political pressures?

A: That's correct.

(*Id.* at 578:1-11.)

\* \* \*

Q. Okay. New Jersey knew that other states had been using their own MAC separate and apart from the Federal upper limit; is that correct?

A. That's correct.

Q. Back in the late 1990s?

A. Yes.

Q. Okay. And what prevented New Jersey from implementing a state maximal allowable cost program?

A: One could attribute it to the political environment in New Jersey, reactions from the provider community.

(*Id.* at 577:8-21.)

\* \* \*

Q. Did -- switching to a different topic. Did New Jersey consider putting in place its own state MAC as opposed to just using the FUL.

A. Eric, I can tell you that we probably have -- have considered that proposal two or three times in my career with the -- with the State.

Q. And why did New Jersey elect not to do that?

A. Same reason as the other times. We had to deal with the political fallout, the strong negative reaction from pharmacies. It just never -- there was never enough support mustered to get that kind of initiative approved in New Jersey.

Q. If -- if you had initiated the MACs that were considered, would you believe that that would have lowered reimbursement payments to pharmacies?

A. Absolutely.

Q. I mean that's why they were protesting it; right?

A. Yes. And you -- you might -- you might actually hear about that kind of initiative in some very short-term future budget periods, so it's still out there. It hasn't disappeared.

Q. And in terms of . . . implementing the MAC, that is something that New Jersey could have done; right, other – other than the fact that they were prevented from doing so by the pharmacy?

A. Absolutely, that would not have been that difficult to do.

(*Id.* at 681:19-683:1.)

Q. Well, it was -- it was clear -- it was clear to New Jersey Medicaid and the providers that whatever MAC was put in place would have -- would have resulted in reimbursement to the pharmacies that it was even lower than whatever the reimbursement was at that time?

A. Yes, that's true.

(*Id.* at 684:9-15.)

(k) When Louisiana Medicaid attempted by emergency rule to reduce pharmacy reimbursement to AWP – 15%, the state legislature overturned the emergency rule by overwhelming vote. (3/31/2008 Terrebonne Dep. at 133:20-141:19, Ex. 25.) Ms. Terrebonne testified related to the overturned emergency rule:

BY MR. TORBORG

Q. Do you recall a time back in early 1989 when the department attempted to enact an emergency rule to lower reimbursement from AWP minus 10.5 percent to AWP minus 15 percent?

A. Yes.

Q. And what happened?

A. Lots of things happened.

Q. Tell me about what happened.

A. I don't know that I can remember everything that happened, but there was an emergency rule to lower the ingredient cost, and there were a lot of complaints and I can't tell you the chronology of events, but Myers and Stauffer conducted a survey, and they determined a reasonable discount off of AWP, and the department did rule making and a state plan amendment and changed the reimbursement formula at that time

\* \* \*

Q. And it says there, in the first paragraph, "Members of the House Health and Welfare Committee voted overwhelmingly to overturn an emergency rule issued by David Hood, secretary of the Louisiana Department of Health and Hospitals, which amended the reimbursement methodology to limit payments for prescription drugs from AWP minus 10.5 percent to AWP minus 15 percent." Do you see that?

A. Yes.

Q. Do you recall that being the case?

A. Yes. There was a lot of activity in 1999.

Q. And this activity that you refer to in 1999 was a result of simply attempting to reduce reimbursement for brand name drugs from 10.5 percent to 15 percent, correct?

A. As it is written here, yes.

Q. Do you have a general idea, Ms. Terrebonne, of what the difference between AWP and AMPs are?

A. I do not.

Q. Do you believe it is more than 4.5 percent for brand name drugs?

A. I don't know.

Q. If it was larger than 4 percent, could one presume that any attempt to use AWP information in the reimbursement methodology would have engendered the same type of activity that you saw in 1999 when you attempted to go to AWP minus 15 percent?

MR. FAUCI: Objection, form.

THE WITNESS: Had they used AMP rather than AWP?

Q. Yes.

A. Perhaps so, yes.

Q. Why would you say that?

A. Because it is always very much a provider issue when there is any change in reimbursement. Providers are very concerned.

(*Id.* at 133:20-134:14, 1401:1-141:19.)

(l) Internal documents, dated in 1997, from the state of Washington contain the following language:

- “cutting [the] % of AWP would be an extreme barrier to access some pharmacies would have to stop serving Medicaid clients.” (Ex. 125 (JDWA-000107-08).)
- “no one can survive a 33% budget cut & continue to provide quality” care. (Ex. 126 (JDWA-000144).)

A 1997 letter from Washington state representative Tom Huff stated that the legislature had the “intent to avoid the drug ingredient payment reduction, if at all possible.” (Ex. 127 (JDWA000233).)

(m) In 1999, Myers & Stauffer provided Wyoming Medicaid with a report that showed that the average acquisition cost for generic drugs without a FUL was AWP – 61.8%. As a result of the Myers & Stauffer report, Wyoming changed its reimbursement rate in 2001 from AWP – 4% to AWP – 11%. Wyoming’s Roxanne Homer testified:

Q. As of 1999, Wyoming Medicaid was aware that the average actual acquisition cost for generic drugs without a [federal] MAC was AWP minus 61.8 percent?

\* \* \*

A. Yes. This would have been in the report that we had. That we had, yes.

Q. (BY MS. LIEBERMAN) Wyoming Medicaid changed its reimbursement rate for prescription drugs in 2001, correct?

A. Yes, that’s correct.

Q. Wyoming Medicaid did not set its estimated acquisition cost at AWP minus 61.8 percent, which was the average actual acquisition cost of which it was aware that providers purchased generic drugs that were not MAC’d, correct?

\* \* \*

A. No, we did not set a separate reimbursement fee for generics at that time.

(12/2/2008 Homar Dep. at 183:2-21, Ex. 128; *see also* Ex. 129 (Roxane WY Ex. 8).) In its State Plan Amendment 01-004, Wyoming Medicaid informed CMS that it arrived at AWP – 11% by using information gathered for the “purpose of determining a reasonable profit” for providers.

(12/2/2008 Homar Dep. at 192:13-14 Ex. 128; Ex. 130 at WY00000074 (Roxane WY Ex. 9).)

At the same time that it reduced the ingredient cost component of its reimbursement formula to AWP-11%, Wyoming simultaneously increased the dispensing fee component to compensate in part for the decrease in reimbursement. Ms. Homer testified:

A. I think that -- to the best of my recollection, we felt like we needed to give at least a small bump in the dispensing fee if we were going to decrease the overall reimbursement related to AWP.

Q. So in making the decision to increase the dispensing fee, would it be fair to say that Wyoming Medicaid considered the dispensing fee portion of reimbursement together with the ingredient portion of the reimbursement formula?

A. Yes.

(12/3/2008 Homar Dep. at 497:22-498:10, Ex. 131.)

(n) In response to threats by chain pharmacies in 2002 that they would discontinue participation in Medicaid, Delaware abandoned a prior proposal to more significantly discount AWP in its reimbursement formula in favor of a lesser discount.

Delaware’s Cynthia Denmark testified the lesser discount was sought to avoid an “access [to care] issue.” (12/9/2008 Denmark Dep. at 150:17-153:17, Ex. 22.)

(o) Oregon Medicaid has historically included a mail order component to its pharmacy program which allows Medicaid beneficiaries to order drugs by mail instead of by visiting a retail pharmacy. (12/16/2008 Anderson Dep. at 129:17-131:2, Ex. 132.) Prior to 2003,

Oregon Medicaid reimbursed vendors dispensing drugs to beneficiaries via the mail order program at the same rates as traditional retail pharmacies. In 2003, Oregon Medicaid solicited competitive bids for vendors wishing to run Oregon Medicaid's mail order program. (*Id.*) Vendors submitted bids with reimbursement proposals of up to AWP - 60%. (*Id.* at 135:19-137:4.) Oregon Medicaid admitted that it could have reduced traditional retail pharmacy reimbursement levels to such a large discount off of AWP, but that there "were political decisions" not to do so. (*Id.* at 141:18-142:8.)

(p) As of 2002, Rhode Island Medicaid had information that actual acquisition cost for generic drugs was on average AWP – 65.93% and WAC – 30.55%, but Rhode Island continued to reimburse providers at a rate of WAC + 5% for at least four more years. Rhode Island's 30(b)(6) representatives testified:

Q. And do you recall we looked at page 7 of this report which relates that the OIG estimated that the invoice price for generic drugs was a national average of 30.55 percent below WAC rather than it being higher, and therefore perhaps supporting that a percentage be added to WAC and the results of their review, quote, show that WAC was not a true wholesale acquisition price and was significantly higher than the actual acquisition costs for generic drugs. Is it fair to say that as of 2002 Rhode Island Medicaid was on notice that WAC was significantly higher than the actual acquisition costs for generic drugs?

\* \* \*

THE WITNESS: Yes.

\* \* \*

Q. So is it fair to say that in 2002 Rhode Island Medicaid was on notice from OIG that WAC could differ from actual acquisition cost to a magnitude of up to 30.55 percent?

\* \* \*

BY MS. RANKIN:

Q. As stated in this report?

\* \* \*

THE WITNESS: Yes.

(Ex. 133 (Roxane Rhode Island Ex. 12); 12/4/2008 Avarista Dep. at 230:17-232:11, Ex. 81.)

When Rhode Island amended its definition of EAC, it moved from WAC + 5% to WAC.

(12/3/2008 Young Dep. at 165:2-20, Ex. 134.)

(q) Larry Iversen testified that South Dakota Medicaid considered changing its estimated acquisition cost from AWP minus 10.5 percent, but decided not to because pharmacies complained that the current reimbursement plan was just covering their costs.

(12/15/2008 Iversen Dep. at 59:2:61:12, Ex. 86.)

(r) In 1998 and again in 2001, Arkansas obtained results of a Myers & Stauffer survey which revealed large spreads between AWP and AAC pricing. (12/10/2008 Bridges Dep. at 206:21-207:18, Ex. 109.) Because of the 1998 Myers & Stauffer survey, Arkansas knew that some drugs could be purchased by pharmacies at rates as high as AWP-90%. (*Id.* at 287:13-17.) Based on the 2001 Myers & Stauffer survey, the state was aware that the AAC for drugs reimbursed under a MAC calculation was AWP-82%, compared to Arkansas' reimbursement rate of AWP-10.5%. (*Id.* at 294:3-297:8.) That same report also showed that average spreads between AWP and AAC for ipratropium bromide was AWP-70%. (*Id.* 329:20-332:19.) Despite the Myers & Stauffer reports and to address provider concerns, the state adopted a reimbursement rate of AWP-20% for generic drugs. (*Id.* at 306:20-307:12.)

(s) Pharmacy associations played an important role in setting reimbursement rates in Tennessee and, in one instance, Tennessee Medicaid's attempt to implement a most favored nation policy with respect to usual and customary pricing was met with strong

opposition from NACDS and abandoned. (Ex. 135 (Abbott Ex. 579); 3/12/2008 Sullivan Dep. at 167:16-170:2, Ex. 1.)

(t)      OIG's Ben Jackson, who worked with the states throughout the 1990s relating to OIG's audits of the difference between AWP and invoice costs, testified:

Q. And what is your view, Mr. Jackson, as someone who has been very involved in this issue in the 1990s about why it is that the state Medicaid programs did not change their reimbursement formulas to match or get closer to your findings?

A. I think I've answered that question already. I mean, I think you've got state legislatures you've got to contend with. You've got lobby groups. You've got state budgets. I mean, there's a lot of things that could play into that.

(12/12/2008 Jackson Dep. 392:6-17, Ex. 37.)

**I.      CMS "Decision Memoranda"**

60.      On or around 2001 to 2002, the CMS Medicaid Pharmacy Team drafted a document titled "Review of Medicaid Drug State Plan Amendments." (Ex. 136 (Abbott Ex. 328.) That document contained the following language:

Recently issued OIG reports indicated that the actual acquisition cost of brand name prescription drug products nationally is an average of AWP less 21.84 percent. Recent discussions with the OIG indicate that they will further refine this number to differentiate it between those single source (brand name drugs) without generic competition and those with innovator multiple source (brand name drugs) with generic competition. The ala indicates that the single source drugs will likely show an average discount of around 17% and the innovator multiple source drugs of around 24%. The OIG also studied generic drug discounts and found that the actual acquisition cost of generic prescription drug products nationally is an average of AWP less 65.93 percent.

\* \* \*

**ANALYSIS**

In recent months there has been an increase in SPAs proposing to change the reimbursement methodology (a listing of these SPAs is

attached). Where there are surveys of costs, the findings generally show that these State's reimbursement could have been reduced by a percentage greater than the proposed AWP discount levels. The lesser level of discount is generally the result of negotiations that occur between the state and pharmacy representatives after the survey results are known. In other cases, the states legislature have responded to the escalating costs of Medicaid drugs by enacting legislation that increases the discount in the ingredient cost or the dispensing fee of these drugs. Legislation usually does not address why these rates are the best estimates or are reasonable.

It is proving increasingly difficult to require the states to establish payment rates in adherence to regulatory requirements. Accordingly, we believe an analysis and an acceptance of other factors states are now using to establish payment rates should be considered in looking at the EAC and the dispensing fee.

We think that the first part of our review should be continuing to rely on the existing review criteria (i.e. survey and rates in other states). For EAC, we would continue to look to surrounding states or because we now think that payment rates vary little nationwide, to a nationwide average. We think it is also helpful to strongly consider approval where the direction of the state's proposed level of reimbursement represents a program savings that does not appear to affect pharmacy participation. Finally, we think EAC needs to include a broader measure of factors that would result in a state agency's best estimate. We could consider the actions of the legislature or negotiations that result in a lower payment rate, even if that rate may differ from other documentation, such as a state survey.

Because the requirements to set dispensing fees are less specific, we would continue to allow states greater flexibility here. For instance, we would permit states to reduce these fees not only to reflect lower costs; but also to permit states to increase them to encourage other program savings measure, such as allowing a higher dispensing fee for the use of generic drugs.

Apart from that, we think a longer-range look at the OIG and state studies as well as a reevaluation of current regulations are in order. If, in fact, there needs to be another basis, such as nationwide surveys that can establish these rates, we need to look at the feasibility and impact of doing so.

*(Id.)*

61. On October 22, 2002, CMS Administrator Tom Scully signed a decision memorandum on the subject of "Review of Medicaid Drug State Plan Amendments." (Ex. 137 (HHD830-000001-04).) That memorandum included the following language:

We are writing to seek your approval for criteria to be used for reviewing state plan amendments (SPAs) that seek to change the payment rates for drugs. There are no explicit statutory provisions for payment rates for Medicaid drugs. States are required to set rates in accordance with regulations at 42 CFR 447.301-333.

\* \* \*

Recent OIG reports estimate the actual acquisition cost of brand name prescription drug products nationally to be, on average, the average wholesale price (AWP) less 21.8 percent. The OIG recently revised this number to differentiate it between those single source brand name drugs without generic competition and those innovator multiple source brand name drugs with generic competition. The OIG estimates that the single source brand name drugs cost, on average, AWP less 17.2 percent and the multiple source brand name drugs cost AWP less 24.4 percent. The OIG also studied generic drug discounts and found that the actual acquisition cost of generic prescription drug products nationally is, on average, AWP less 65.9 percent. Industry sources indicate that nationally, higher profit margins are obtained on generic prescription drug products. . . .

### ANALYSIS

In recent months, there has been a significant increase in the number of SPAs proposed which would change the reimbursement methodology. State cost surveys have generally showed that state reimbursement could be reduced by a percentage greater than the proposed AWP discount level. The discount level has usually been reduced as the result of negotiations between the state and pharmacy representatives after the survey results are known. In other cases, the state's legislature has responded to the escalating costs of Medicaid drugs by enacting legislation to increase the discount in the ingredient cost or decrease the dispensing fee. Legislation usually does not address the basis for the ingredient cost reduction or the reasonableness of the dispensing fee,

It is proving increasingly difficult to require states to provide statistical data to support their proposed payment rates. In addition,

we believe that other sources of information and other factors can be used to evaluate the appropriateness of payment rates.

As an alternative to requiring states to provide surveys or statistical data to support their proposed rates, we would ask states to compare their proposed rates to those of other states. For EACs, we would broaden our comparisons from surrounding states to all states because the market for drugs is national. In order to provide states with current payment rates of other states, we will maintain a list of each state's current EACs and dispensing fees on the CMS Web page. (For dispensing fees, we will put more weight on other states in the region, as these cost may differ by geographic cost differentials.) In short, we will look favorably on proposals to reduce reimbursement when there is a basis to conclude that the reduction will not affect pharmacy participation.

Finally, we will approve rates set by the legislature or through negotiations, even if the rate differs from that suggested by other documentation, such as the rates of other states or from a state survey.

Because the regulations on dispensing fees are less specific (i.e., the standard is "reasonableness"), we would continue to allow States greater flexibility here. For instance, in addition to allowing states to reduce these fees to reflect lower costs, we would also permit states to increase or vary their rates in order to provide incentives to pharmacists to dispense less costly drugs, such as by allowing a higher dispensing fee for dispensing generic drugs.

(*Id.*)

62. With respect to the CMS "Review of Medicaid Drug State Plan Amendments" decision memorandum, CMS's Dierdre Duzor testified:

Q. Ms. Duzor, I've handed you a copy of what we've marked previously as Exhibit Abbott 328, a document entitled Review of Medicaid Drug State Plan Amendments. I ask you to take some time and look at that document.

A. Okay. (Reading.)

Q. Ms. Duzor, have you had a chance to look at that document?

A. Yes, I have.

Q. Can you tell us what this document is?

A. This document –

Q. Let me strike that. Are you familiar with this document first?

A. Yes. I recall the document.

Q. Can you tell us what it is?

A. I believe it is a draft of a decision memo seeking guidance from policymakers in CMS on approaches to reviewing state plan amendments that were proposing to revise either the ingredient cost payment for drugs or the dispensing fees.

Q. What is a decision memo?

A. A decision memo is an issue paper with recommendations to take to policy decision makers. Options and recommendations generally.

(10/30/2007 Duzor Dep. at 176:16-177:17, Ex. 38.)

\* \* \*

Q. What did you believe on a national level was the rate of discounts from AWP for generic drugs?

MS. MARTINEZ: Objection to form.

A. We knew that for generic drugs that AWP minus 13 was a generous payment based upon the IG's findings.

(*Id.* at 191:19-192:3.)

63. Ms. Duzor acknowledged that HCFA and CMS gives state legislatures deference when reviewing state plan amendments. (3/26/08 Duzor Dep. at 782, Ex. 54.) Duzor testified that if a state told CMS that its legislature had authorized a state plan amendment, that alone was a sufficient reason for CMS to approve the change. In those cases, CMS would not inquire into exactly why the legislature did what it did or the process it followed. (*Id.* at 589-90.) Duzor stated that she was aware of “pretty intense lobbying in state legislatures” by pharmacies and their representatives on the topic of drug reimbursement. (2/27/08 Duzor Dep. at 410-11, Ex.

82.) Duzor surmised that Medicaid officials preferred to allow the existence of a spread due to lobbying and political pressures that make it difficult for states to reduce reimbursement:

Q. Do you have any understanding of why these state Medicaid officials prefer to submit reimbursement formulas for reimbursement costs that allow the existence of the spread?

THE WITNESS: I believe that they, like us, are trying to reduce the amount of the reimbursement, but there are economic and political realities in a state that make it difficult.

\* \* \*

Q. What are those economic and political realities?

A. That the pharmacies that are benefiting from the spread are politically powerful and oppose any reductions.

\* \* \*

Q. Well, is it your understanding that the state pharmacy directors are generally aware about these -- of these OIG reports?

A. Oh, yes.

\* \* \*

THE WITNESS: I do believe they are. We have sent them to state Medicaid directors.

...

Q. So then it's fair to say that the state officials responsible for state Medicaid policy that deal with the legislatures are aware of these 40 percent and potentially higher spreads on generic drugs, correct?

\* \* \*

THE WITNESS: I believe that the state pharmacy directors are, and probably most state Medicaid directors are.

\* \* \*

Q. Why do you believe the state Medicaid agency chooses to recommend plans that allow spreads to be paid for generic drugs --

\* \* \*

Q. -- on the order of 40 percent or higher?

\* \* \*

THE WITNESS: Because they have to have the approval in their executive branch and frequently in their legislative branch to change the way they pay pharmacists. And they don't get support for dramatically lower reimbursement rate.

(3/26/08 Duzor Dep. at 651-55, Ex. 54.)

64. Ms. Duzor further testified that, although OIG reports showed discounts of over 60 percent below AWP for generic drugs, CMS continued to approve state plan amendments that allowed reimbursement at AWP minus 15 or AWP minus 20 "[b]ecause they're moving in the right direction. They're reducing pharmacy reimbursement and saving the states and the federal government money by doing so." (*Id.* at 646:18-647:9.) CMS approved these state plans even though it was aware for some time based on OIG reports "that the pharmacies [were] making money on the difference between what they're acquiring the drug for and what they're reimbursing it at in the case of generics." (*Id.* at 646-47.)

65. Regarding how states are currently reimbursing for generic products, Ms. Duzor stated:

A. Providers are being paid based on a formula that is a discount off of AWP or a small add-on to WAC. I mean, the idea that you're saying that states are paying them the spread, I don't think that we view it or that states view it in that way. Their payment methodology has that result.

Q. Okay. And you're aware of that result today, correct?

A. Yes.

Q. And so CMS is not being fooled about anything when it comes to the fact that they are paying a spread for generic drugs today?

...

A. There was testimony before congressional committees. There was the enactment of the DRA. All of that was in recognition of

the fact that the AWP's were not good estimates of real cost and that Medicaid is paying too much for drugs.

(2/27/08 Duzor Dep. at 330-32, Ex. 82.)

\* \* \*

Q. And you know that the state Medicaid plans reimbursement methodologies now are reimbursing at rates nowhere close to that amount; isn't that right?

...

A. The state of Washington is doing pretty well at AWP minus 50. But they are the exception for generics.

Q. And that's only for drugs that have five or more labelers or manufacturers, correct?

A. Yes. That's true.

Q. Not for all generic drugs?

A. Right.

Q. And they're the exception.

A. Yes, they are.

(10/30/07 Duzor Dep. at 238, Ex. 38.)

66. Kim Howell began working for CMS as a senior drug policy analyst in September 2000. (4/22/08 Howell Dep. at 67-68, Ex. 138.) Howell was a medical care programs supervisor for Maryland's Medicaid programs from 1994 to 2000. (*Id.* at 31-32.) Howell explained that higher officials at CMS, such as Larry Reed, could approve state plans even if the state's supporting documentation did not justify the amendment:

Q. And if you had not received that documentation to support the reimbursement methodology as the best estimate, yet still approved it, then CMS didn't do its job?

\* \* \*

A. No. Then the recommendation from the analyst would have went to Larry Reed as to this is what the state is proposing, this is what the state has provided to us. And then it was Larry Reed's responsibility to take it to the authorities above him to provide them with the issue and they would make the decision.

Q. So if there was going to be an exception to the rule it has to get done above you?

\* \* \*

A. Exactly.

Q. And we saw that in Wisconsin such an exception happened?

\* \* \*

A. The state plan was approved.

(*Id.* at 248-249.) Howell explained that because of the disparity between the proposed reimbursement levels in the state plan amendments submitted to CMS and the data available to CMS regarding drug costs, she sought guidance from higher-ups within HCFA:

Q. And the state plans that were being submitted to you, the state plan amendments that were being submitted to you, were not in your view setting forth reimbursement methodologies that were consistent with the data that you had; is that fair to say?

A. Yes. That's correct.

Q. And because of that, the difference between what was being submitted and the regulations, you wanted to get approval from someone higher than you?

A. It's not that we wanted. We needed to have guidance from the management of CMS.

(*Id.* at 275-276.) Ms. Howell drafted the first draft of the "Review of Medicaid Drug State Plan Amendments" document. (*Id.* at 270-71; Ex. 136 (Abbott Ex. 328).) With respect to that document, Ms. Howell testified:

Q. If you would go to the second page of the decision memo, you wrote there at the top "Analysis: In recent months there has been an increase in SPAs" that means state plan amendments?

A. State plan amendments.

Q. “Proposing to change the reimbursement methodology (a listing of these SPAs is attached). Where there are surveys of cost the findings generally show that these state’s reimbursement could have been reduced by a percentage greater than the proposed AWP discount levels.” And that’s something that you had seen personally?

A. This is the problem that the entire team was seeing. So it’s just not based on the state plans that I personally was reviewing. This was what the other analysts, the problems they were seeing also.

(4/22/08 Howell Dep. at 277 278, Ex. 138.)

67. With regard to how CMS responded to OIG’s reports on the differences between AWP and invoice costs for drugs, OIG’s Ben Jackson testified:

Q. I believe you testified that in conversations with legislators and their staffs you indicated that you were at times critical of CMS, right?

\* \* \*

A. I think we felt as an agency that CMS could have done more with the states, yes.

(12/12/2008 Jackson Dep. at 388:7-10, 18-19, Ex. 37.)

**J. The States’ Responses To The DOJ AWPs**

68. On April 21, 1999, Congressman Pete Stark of the U.S. House of Representatives Committee on Ways and Means sent a letter to HCFA Administrator Nancy-Ann Min DeParle that included the following statement:

I urge you to take a simple and easy step to counteract an ongoing fraudulent practice by some pharmaceutical manufacturers that is costing Medicare and Medicaid hundreds of millions of dollars in excessive reimbursement payments. It is my understanding that HCFA and various antifraud units of the government have been working with a company known as First Data Bank to make available more accurate drug pricing information. If my understanding is correct, I request that you immediately issue

written guidance to the States' Medicaid Programs approving their use of First Data Bank's agreed reporting of more accurate prices in calculating reimbursement amounts for certain injection, infusion and inhalation drugs and biologicals. I also request that you take similar action to insure that the Medicare carriers have access to and use the more accurate First Data Bank prices for the drugs and biologicals in question.

(Ex. 139 (Abbott Ex. 136).) On April 26, 1999, DOJ's T. Reed Stephens faxed Mr. Stark's letter to Mary E. Riordan, Office of Counsel to the Inspector General, with the following note: "Letter from Congressman Stark to HCFA administrator last week. Stark is not aware of the *qui tam* but apparently is aware of our contacts with First Databank." (*Id.* at 2.) On April 27, 1999, Ms. Riordan faxed Mr. Stark's April 21, 1999 letter to Bob Niemann, CMS Drug Payment Policy Analyst (Medicare) and Larry Reed, Technical Director, CMS Medicaid Division of Pharmacy. (*Id.* at 1.)

69. On February 16, 2000, Patrick E. Lupenetti, a member of the NAMFCU Drug Pricing Team, sent a letter to Medicaid Pharmacy Directors concerning a national investigation by State and federal agencies regarding drug pricing and an effort to work with First DataBank to improve the accuracy and validity of pricing information provided for a limited number of medications – generally infusion, inhalation, and injectable products. (Ex. 140 (Abbott Ex. 137).) The letter indicated that "the substance of this proposal has already been outlined to State Pharmacy Directors, particularly at your July 1999 national conference, in a presentation in which Assistant United States Attorney Reed Stephens, HHS-OIG Associate General Counsel Mary Riordan, Maryland MFCU Director Carolyn McElroy and most State Pharmacy Directors participated." (*Id.*)

70. On May 1, 2000, First Databank provided new average wholesale prices (hereafter, the "DOJ AWP") for approximately 400 NDCs. (Ex. 141 (Abbott Ex. 184).) The

400 NDCs represented 51 injectable, infusion, and inhalation drugs, including Abbott's vancomycin, dextrose, and sodium chloride. (*Id.*)

71. On September 2001, the Office of Inspector published a report, titled "Medicaid's Use of Revised Wholesale Prices" (OEI-03-01-00010), that analyzed whether the State Medicaid programs were utilizing the DOJ AWP. (Ex. 142 (Abbott Ex. 95.)) The report contained a chart that purported to show whether each state "Uses Revised Prices for Pharmacy Drugs," "Uses Revised Prices for Physician Drugs," and "Subtracts Discount for Revised Price." (*Id.* at 10-11.) The chart indicated that 20 states did not use the DOJ AWP for any Pharmacy Drugs, and another eight Medicaid programs (Alabama, D.C., Idaho, Kansas, Ohio, Oregon, Texas, and Wisconsin) that did not use the DOJ AWP for certain drugs. (*Id.*)

72. In its response to a draft of OIG's report on Medicaid's Use of Revised Wholesale Prices, CMS included the following statement:

The OIG concludes that because most states base their reimbursement for drugs on AWP, inflated AWP have "caused Medicaid to overpay for these products." (See pages ii (Conclusion) and 9 (first paragraph.)). Since the regulations and relevant state plans authorize payment for drugs based on AWP, regardless of whether those prices are inflated, we have concerns with the statement that states and Medicaid have "overpaid" for drugs. We therefore recommend that the sentences on pages ii (penultimate paragraph, second sentence) and 9 (first paragraph, second sentence) be deleted.

(*Id.*). OIG deleted the language referenced in CMS's comment in the final draft of its report.

73. In its project to assist Dr. Duggan with information on how the state Medicaid programs paid providers for dispensing drugs, Myers & Stauffer also analyzed the states' use of the DOJ AWP. Myers and Stauffer found five states (Delaware, Idaho, Indiana, Oklahoma, and Pennsylvania) that OIG's report indicated were utilizing the DOJ AWP, but for which they were unable to verify use of the DOJ AWP, and another two states (Illinois and Montana) which

eventually stopped using the DOJ AWP's. (Ex. 143.) OIG's report identified four states (Kentucky, Minnesota, Missouri, and North Dakota) that "used the DOJ AWP's at one time, but no longer do[] so." (Ex. 142 at 10-11 (Abbott Ex. 95).)

74. Missouri is one of a number of states that implemented the DOJ AWP's, but later reversed its decision. In June of 2002, Missouri's Office of State Auditor wrote a performance audit titled "Cost Containment for State Drug Expenditures." (Ex. 144.) The report contained a discussion of Missouri's use of the DOJ AWP's, including the following language:

Within 2 months of Department of Justice notice of the more accurate average wholesale prices, Utah officials began using the lower drug prices with new dispensing fees. With the help of infusion specialty providers, Utah officials categorized the 437 drugs into 5 groups appropriate to the preparation and overhead costs for the product. The new dispensing fees set up for drugs in 4 of the 5 categories ranged from \$8.90 to \$33.90 per prescription.

Missouri officials initially implemented the more accurate prices for provider reimbursement using the normal \$4.09 dispensing fee, which was not designed to cover these drugs. Division officials reversed the decision after home infusion providers threatened to cease services due to insufficient dispensing fees. Provider personnel admitted the former reimbursement rates exceeded their product acquisition costs, but they used the excess reimbursement to offset the higher dispensing costs of home infusion drugs. Division officials indicated they plan to use these lower prices again after determining adequate compensation for home infusion services. While no implementation date has been set, the Division Director stated the necessary changes to implement these prices would be part of the division's fiscal year 2004 budget proposal.

(*Id.* at 9.)

75. Similarly, California Medicaid did not adopt the DOJ AWP's. A document produced by California contains the following language regarding why California did not adopt the prices:

- "Accepting these new AWP's as the basis for provider reimbursement in Medi-Cal is a serious policy consideration. This change would result in dramatic decreases in the reported AWP for approximately 400 drugs—decreases of as

much as 80% in some cases. The new AWP reductions apply to drugs which are usually administered in physicians' offices or clinics. However, the same drugs are often administered at patients' homes via pharmacy dispensing and home health care administration."

- "The Department is concerned that providers affected by the new AWPs may discontinue serving FFS Medi-Cal patients if the new prices are implemented. If this occurs, patients would either not have access to these important drugs or patients would be directed to a hospital to obtain them."
- "Department staff recently participated in a national teleconference on this subject involving other state Medicaid pharmacy programs. Many pharmacy program administrators indicated that they were not implementing the new AWPs at this time because of concerns over provider discontinuation and resultant patient access problems."
- "We recommend that Medi-Cal not implement the new price reporting mechanism due to the serious impact on both the providers and beneficiaries."

(Ex. 145 (Gorospe Ex. 14 (3/19/08 Dep).) California's Kevin Gorospe confirmed that California did not adopt the DOJ AWPs out of concerns over access. (3/19/08 Gorospe Dep. at 198:7-201:14, Ex. 20.)

76. CMS's Larry Reed testified about the DOJ AWP project:

Q. Do you recall that starting in 1999 or thereabouts the Department of Justice began to discuss with HCFA and the states the possibility of using more accurate average wholesale prices that they had developed?

MS. MARTINEZ: Objection, form.

A. No. I don't recall that type of effort, an overall effort to get a more accurate AWP.

Q. You don't recall anything about that effort at all?

A. No. There was a specific effort for a specific manufacturer, but I don't recall this effort.

(3/18/2008 Reed Dep. at 780:16-781:7, Ex. 146.)

77. Susan Gaston, Health Insurance Specialist at CMS from 1991 to 2003, testified that the DOJ AWP effort was “the result of a litigation suit.” (3/19/2008 Gaston Dep. 397:10-398:3, Ex. 147.)

78. Evidence indicates that some states believed that the “DOJ AWP effort” was an effort to redefine AWP. On June 22, 2000, Minnesota’s Cody Wiberg sent an e-mail to the National Medicaid Pharmacy Administrators wherein he stated:

While the legislators did not define AWP, we believe that their intent was to use “AWP” to mean a single estimate of wholesale price as published in a compendia such as Redbook or First DataBank. My understanding is that FDB is now publishing two sets of “AWPs” for the 428 drugs in question – one for Medicaid agencies and one for everything else. The fact that the legislators chose to estimate actual acquisition costs at AWP-9% indicates that they were aware that the single, published AWP was actually higher than the price for which most pharmacies could buy drug products. Had they known that AWP would be reduced to AAC, they would not have established a 9% discount off of AWP.

\* \* \*

Some public and private third party payers have purposely kept the dispensing fee low precisely because there is a spread between AWP and AAC. In fact, when pharmacy organizations have sought an increase in dispensing fees, the AWP spread has been pointed out to legislators. It is true that ingredient reimbursement is supposed to be based on estimated acquisition cost. The ancillary costs of dispensing the drug are supposed to be accounted for by the dispensing fee. If the AWP spread disappears, the dispensing fee may have to be increased, especially for many of the 428 drugs currently in question. Many of these drugs require some type of compounding or other preparation.

(Ex. 148 (Abbott Ex. 492); *see also* Ex. 149 (Abbott Ex. 584).)

**K. State MACs**

79. State officials testified regarding the source of pricing information they used to establish MACs:

(a) Tennessee’s H. Leo Sullivan testified:

Q. Now where would you get the information that you would use in the MAC program regarding what pharmacists were—pharmacies were actually paying for drugs?

A. My, my system was, was not very sophisticated or very scientific, but nonetheless believe it to have been very effective. What I did was, I knew I had a contact within the largest generic distributor in our area, and one of the most—one of the more popular. Again during this time that I, that I was setting MAC prices, rather than MCOs or PBMs, the, the best deal on generic weren't coming from, from big wholesalers. They were coming from generic distributors. So I had contacts within this one particular company who would tell me, who would first of all keep me apprized any time they, they were able to distribute new generic drugs, also give me information if, if there was some problem with an existing generic drug's availability, and also tell me and give—send me catalogs that they sent to the pharmacists and then tell me additionally what am I looking at for this drug X, Y, Z, what does a hundred of them cost a pharmacy? I didn't look at Red Book or Blue Book or First Data; I called the people that sell it. . . .

(3/12/2008 Sullivan Dep. at 106:18-107:22, Ex. 1.)

\* \* \*

Q. But you used a MAC program to reimburse generic drugs; is that right?

A. Yeah. Now I thought you were talking about brand name in your original question. I keep the two totally separate. I have never reimbursed anybody for generic based on AWP.

Q. So would it be fair to say that you believed you had another choice to set reimbursement rates for generic drugs?

A. Oh, yes.

Q. Apart from the compendia.

A. Yes. Yes. I'm sorry.

(*Id.* at 115:20-116:10.)

(b) Ohio's Robert Reid testified:

Q. So the prices that you used to set the MAC amount, those were based on actual prices that you got from pharmacies; correct?

A. Right.

Q. They are not based on—

A. Well, partly, yeah.

Q. What else were they based on?

A. Well, we would take the First DataBank price into consideration, although rarely use it on the grid, unless it was reasonable, comparable.

Q. So if the First DataBank price was not comparable to the other prices, you wouldn't use it?

A. No. I would consider it to be an outlier.

Q. If it was an outlier, it wouldn't even go into the 65th percentile calculation?

MS. GEOPPINGER: Object to the form of the question.

Q. You can answer.

A. Yes.

Q. And you did all this by yourself?

A. I did it all by myself up until 2001.

(12/15/2008 Reid Dep. at 160:19-161:20, Ex. 2.)

(c) Maryland's Joseph Fine testified:

Q. So you got pricing information from either wholesalers or a pharmacist who cooperated with the department in giving—

A. But it was from wholesalers. It was always wholesale prices. It was the wholesaler file. But since they wouldn't let us use it directly we had to go through them to get the files.

Q. When you say wholesale file—

A. Meaning the price list. The drug price list.

Q. We're not talking about the compendia here?

A. No. Maryland did not use compendia, meaning we did not use First Databank and/or Medi-Span to set our IDC. We were

determined to set our state MAC or IDC based on what local—what our pharmacists could get the drug for if they were working and buying the product from a wholesaler that was selling in Maryland.

Q. And this process of going to get wholesale price lists from either a wholesaler or a pharmacist, some of that was just part of your job, right?

A. Correct.

Q. Something you felt you needed to do to get fair pricing for drugs?

MS. YAVELBERG: Objection, form.

A. Well, the feel—it's not my feeling. It's what Maryland decided to do to get fair pricing to their pharmacists who fill prescriptions for Maryland medical assistance recipients.

Q. And you received cooperation from the pharmacy providers in this effort?

MS. YAVELBERG: Objection, form.

A. Yes. Yes. The pharmacy providers worked with us.

(12/9/2008 Fine Dep. at 203:8-204:19, Ex. 91.)

(d) Nebraska's Gary Cheloha testified regarding how Nebraska established

MACs:

Q. Once you determined that there's a particular drug that you'd like to set a maximum allowable cost for, how do you go about setting that actual price?

A. Ask for a recommendation from Pace Alliance. We'll also call pharmacies to determine the range of costs or range of recommended—recommendations for SMAC pricing.

Q. Okay. So if you find out from Mr. Woods at Pace that, for a particular prescription drug, that he can purchase it for, say, 50 cents for that particular dosage, I mean, do you use that figure? Or is there a calculation involved in taking that number and turning it into a MAC?

A. Into an actual SMAC price?

Q. Uh-huh.

A. There is no set formula, and he doesn't provide us—I think he has—I believe he has confidentiality agreements for the actual price that the Alliance members can purchase the drug for. So—and we rely mostly on the Pace recommendations.

Q. So he'll give you kind of a range, and you'll—

A. He'll generally quote a specific price. He'll say 8 cents, 10 cents. I recommend this for the SMAC price on it.

Q. And do you know—you said that there's some confidentiality provisions as far as what they're actually paying. Do you know if he bills in some percentage or a few cents here or there to make sure that other people can get that or to account for profit or anything like that?

A. All I would know for sure is that it's more than the contract price, but I don't know whether he uses a specific formula or how he specifically determines that. He—from time to time, on a very limited basis, he and I have discussed—how will I say it—the price that the pharmacies pay. And then I would—when I was doing it, I made a determination of where to set the MAC price, at something above that.

Q. And did you have a formula, or you were just—it was a case-by-case basis for—

A. Generally, a case—it was a case-by-case basis. I did not have a set formula.

Q. And I'm assuming that the—you said that Pace is a purchasing organization that has pharmacies in Nebraska, and those pharmacies are participants in the Medicaid program?

A. Yes.

(12/2/2008 Cheloha Dep. at 128:13-132:17, Ex. 28.)

(e) Michigan's Sandra Kramer testified that a pharmacist consultant provided utilization data on generic drugs to help establish Michigan Medicaid's MAC prices:

Q. Were you responsible from 1990 through the time you left for setting state MACs?

A. Yes.

Q. Okay. How were those set during that time period?

A. During that time period, the best that I can recall is that we had a pharmacist consultant with the department. I don't remember how frequently he came in, but periodically he would come in and I would provide him with utilization data on the generic drugs and he would do research of maybe what other states or another insurer would have priced MAC at, and then also he would have availability of wholesaler information and would establish target MACs, and then I would take those target MACs and publish them in drafts for comment with the pharmacist and other people that were interested in pharmacy issues.

\* \* \*

Q. And did this—you stated this pharmacist consultant had access to wholesale prices?

A. He was a practicing pharmacist.

Q. So he knew what his actual acquisition costs would be for particular drugs?

A. I assume so. . . .

(3/25/2008 Kramer Dep. at 144:10-145:21, Ex. 4.)

(f) Georgia's MAC rates are set by its PBM pursuant to the PBM's proprietary formula. (12/15/2008 Dubberly Dep. at 207:3-208:8, Ex. 24.)

(g) New Hampshire state received MAC prices from its pharmacy benefit manager, First Health Services, which used a proprietary formula to calculate MAC prices.

(10/29/2008 Clifford Dep. at 66:11-67:10, Ex. 106.)

(h) Since at least July 2002, Illinois Medicaid has considered pharmacy acquisition cost information as part of its MAC program. (Ex. 150 (Roxane IL Ex. 10). "DHFS would review pharmacy acquisition cost information to verify that the products were available at or below the MAC price." (*Id.*, at 5)

(i) Washington Medicaid determined its state MACs based on surveys of the three largest wholesalers' prices in Washington and negotiations with the Washington State Pharmacy Association. (11/24/2008 Wimpee Dep. at 105:9-107:13, Ex. 151.) An internal Washington Medicaid document stated that MAC were set after discussions with pharmacists to assure that MAC prices were "workable, fair and consistent." (Ex. 152 (JD WA 1570-87).) In 1997, Washington implemented an automatic maximum allowable cost ("AMAC") methodology to compute state MACs not otherwise on Washington's MAC list. Under this methodology, "AMAC reimbursement for all products within a generic code number sequence shall be at the estimated acquisition cost (EAC) of the third lowest priced drug in that sequence, or the EAC of the lowest priced drug under a federal rebate agreement in that sequence, whichever is lower." (Ex. 153) (HHC018-0045-50).)

(j) According to Jude Walsh, former Division Director for Health Care Management for Maine Medicaid, Maine requests invoices from pharmacies and reviews the invoice prices in the process of setting MACs.

Q. Do you know how the state went – goes about setting a MAC?

A. Yes.

Q. And how does it do that?

A. We look at the number of generic manufacturers. It is typically for generics, the generic manufacturers that are producing medications. We look at invoices to see the spread between the reimbursement and the acquisition, and we – we implement caps on the – setting caps for the maximum amount that we'll reimburse for those drugs.

(3/26/2008 Walsh Dep. at 94:5-16, Ex. 154.)

\* \* \*

Q. And do you – what do you mean by acquisition cost?

A. The amount of – the amount of money it costs the pharmacy to acquire a medication.

Q. And how would Maine determine that?

A. We – we ask for invoices.

Q. You ask for invoices in the process of setting a MAC?

A. We do because we have pharmacies that complain that our MAC's are too low and we say send us an invoice so we can see.

Q. How often does that occur?

A. We set our MAC's monthly. We are always updating our MAC list.

Q. Do the pharmacists call pretty regularly then?

A. If they have a concern.

(*Id.* at 97:20-98:14.)

(k) Arkansas Medicaid established its MAC calculation based on invoice prices that pharmacies share with Arkansas Medicaid in order to approximate the actual acquisition cost. (12/10/2008 Bridges Dep. at 65:3-11, 244:14-246:1, Ex. 109.)

(l) North Dakota's Brendan Joyce testified:

Q. Okay. And do you know how Chad Jones sets MAC prices for the department?

A. He evaluates actual acquisition costs from surveys that -- wholesalers that he's -- has contacts with. So he contacts wholesalers to get the actual acquisition costs of products. Compares his MAC pricing to other MAC price lists that are out there and available. And he tries to set the MACs at a rate that will encourage generic utilization, yet -- and also give appropriate adequate reimbursement based on the formula, the rest of the reimbursement formula with the state.

Q. During the time North Dakota Medicaid set its own MAC prices it did not rely on AWP to set those prices, correct?

A. We still set some of our own MAC prices. So --

Q. Okay.

A. We do -- we have not -- never have and never will care what the AWP is. In the setting of those MACs.

(12/12/08 Joyce Dep. at 128:21-129:20, Ex. 19.)

80. State officials provided testimony regarding the factors that influenced how their states established MAC pricing levels.

(a) Florida Medicaid's Jerry Wells testified:

Q. When you established those MACs, were you trying to set the MAC at exactly the acquisition cost of providers or at some point above or below the acquisition cost for providers?

A. We would not have tried to set acquisition or the reimbursement level below acquisition cost. We would try to set the reimbursement level at a point where 95 percent of the providers could purchase the drug at or below that price.

(12/15/2008 J. Wells Dep. at 229:22-230:10, Ex. 12.)

(b) Tennessee's H. Leo Sullivan testified:

Q. And do you know in Tennessee, either before TennCare or after TennCare was paying a compounding fee for IV? Do you know if that was something that was being paid?

A. Ah, no. But there's, there's ways to pay it without, without having a separate—you know, I noticed on here that one form is for payment, one form is for reimbursement of supplies, one form is for—you know, they're, they're making a variety to submit multiple forms. And I wouldn't—I can't tell you a specific product or specific time period, but one of my strategies was in issues like this, where compounding was involved, I didn't want to go down the road, at least in the early Nineties, of getting into paying for compounded prescriptions, because that can—that could range from a sterile product all the way down to an ointment, okay? And, and our claims reimbursement system hadn't evolved to the current NCPDP sophistication of today. So it was very hard to put in a, a set compounding fee for what, what products? One may take a minute to make, one may take an hour and a half. So getting back to, to the MAC issue, some, sometimes for certain products in this arena, you would take that into account for the MAC. For example, I might say, I'm not paying for the tape that you use to hold the IV

needle into place. I'm not paying for the IV needle or the tube set. I'm not going to—I don't want bills for that. I know you've got to do it to administer this drug. So we're going to add on the cost of this drug X, because I know this, this and this always goes with it, and I know there is a fixed cost for that, but I don't want five bills. I want 10 different places. Bill me for the drug. And I'll make sure that the—whatever the MAC is incorporates all your other costs. And you have to talk with providers and know what that is. I mean, you know.

Q. So, in short, you would use the payment for the drug itself to cross-subsidize other things that might need to be paid to fairly—

A. And that would include compounding.

Q. And it may include nursing services that were not included, things of that nature?

A. (Nodding yes.)

(3/12/2008 Sullivan Dep. at 152:16-154:22, Ex. 1.) According to Sullivan, Tennessee encouraged the use of generic drugs over brand drugs by including a higher profit margin into reimbursements for generic drugs, which was also a way to save the state money. (*Id.* at 60:12-61:14; 62:13-63:10.)

(c) Washington's Ayuni Hautea-Wimpee, the Pharmacy Unit Manager for Washington Medicaid, testified:

Q. And when setting AMAC, you would look at pricing available to wholesalers?

A. From wholesalers, yes.

Q. Excuse me, from wholesalers?

A. Um hum.

Q. In Washington State?

A. Yes.

Q. Okay. And you would look at an array of those prices and determine at what price pharmacists could actually obtain the product for?

A. Correct.

Q. And you mentioned that one concern was access; is that correct?

A. Yes.

(11/24/2008 Wimpee Dep. at 108:4-18, Ex. 151.)

(d) Minnesota's Cody Wiberg testified:

Q. Mr. Wiberg, I'd like to -- or Doctor Wiberg. I apologize for that. I've been calling you "Mr." all day. I would like to take you back to the Zantac example you gave earlier.

A. Yes.

Q. I think you said the AWP was 90 cents.

A. Around there, yeah.

Q. The MAC was about 25 cents, and the AAC was about 6 cents, right?

A. Well, the -- the actual acquisition costs for the store I worked as was -- was -- was around 6 cents, as I recall.

Q. So 25 cents is what the State Medicaid Program chose to pay for that 6 cent pill, right?

A. That's correct.

Q. Isn't that about a 400 percent spread, between 6 and 25?

A. Well, again, you can't -- people don't spend percentages. They spend dollars. And what the goal was -- and I don't have a calculator handy, but if you do the math, typically we're talking about 60 tablets. In a typical prescription. So, you know, the actual math is -- is they're not getting huge amounts of actual dollars. And at some point, I think we reduced the MAC. Part of -- well, let me just say that when I came on board at the Minnesota Department of Human Services, there was one pharmacist working. We used the pharmacy program manager, he was working there by himself. He had three rebate analysts. There had been more

pharmacists working for the Department earlier, but they worked in different divisions. In fact, there wasn't a pharmacy program a year-and-a-half before I started. There was no coherent Pharmacy Management Policy. And as a result of that, we made -- after I took over, we ended up making massive changes. It went from, in my opinion, being a program that was not very effectively managed, to being one that is very aggressively managed now.

So -- and the other issue that we had -- I mentioned earlier was that my predecessor, because he introduced this language that ended up getting amended, took away our authority to do a lot of things with -- with MACs. So part of what we were trying to do, although we had to accelerate when we got to 2002 and 2003, we had no choice. Part of it was to not shock the system, which had essentially been unmanaged. So we're trying to introduce these changes in a -- I wouldn't say gradual, but we're trying to not hit people with so many things at once that we cause disruptions to service, or that, quite frankly, because it's a political environment, that it backfires on us, and we do have people going to the legislators, saying, basically, these people over at DHS are out of control, and have our authority to make the changes we thought were necessary taken away from us. So we didn't always do things initially as aggressively as we might have in the time frame we're talking about here, 2000, 2001. 2002, 2003, when we're starting facing budget deficits, even before then, we had started ramping up and doing preferred -- you know, our own internal preferred drug list for some categories. But we got very, very aggressive at that point. And so these days, as I mentioned earlier, we increased the use of generics because of the MAC program from about 50 percent when I started to 60 percent. It's now up to 69 percent. So -- you know - - anyway.

Q. But in these generics MACs that you're setting are shooting for a dollar amount spread --

A. Right.

Q. -- not necessarily for a correct percentage spread, right?

A. That's correct.

Q. And the correct percentage could be a thousand, could be 2,000, could be 1 percent, depending upon the starting cost of the product, right?

A. Yes, we are searching for a dollar spread, not a percent spread.

(3/14/2008 Wiberg Dep. at 356:19-360:13, Ex. 68.)

(e) South Dakota's Larry Iverson testified:

Q. If you look at the second bullet point at the third sentence, it states, "The MAC price is then applied across all package sizes available, but is structured to insure that the profit to the pharmacist to dispense the generic product is higher than that associated with dispensing the brand product. This strategy provides pharmacists with an incentive to dispense generic products as well as to make recommendations to prescribers that they substitute brand products with generic therapy alternatives." As we established earlier, providing the provider with a profit was an important concern to South Dakota Medicaid, correct?

A. Yes.

(12/15/2008 Iversen Dep. 99:15-100:8, Ex. 86; Ex. 113 (Dey Ex. 911).)

(f) Ann Rugg, former Deputy Director of Vermont Medicaid and Vermont's

30(b)(6) witness, testified that Vermont Medicaid set MAC prices that would ensure profit to providers:

Q. Well, your explanation that you just stated on the record, would you say that that is the rationale for Vermont also implementing the MAC program?

A. The reason Vermont wanted to implement a MAC program was to manage the price of generics at a level using this particular model at a level where a store could still make a profit, yet that the program itself would not be paying an exorbitant rate.

...

Q. And you also testified that some sort of profit or reasonable profit was – well, let me rephrase that question. Was it Vermont's goal also to ensure some sort of reasonable profit for pharmacy providers?

A. Yes.

(12/15/2008 Rugg Dep. at 210-212, Ex. 156.)

(g) Maryland produced a document titled “Proposed Sliding Scale Reimbursement Formula For Generic Drugs.” (Ex. 157 (Abbott MD Ex. 17).) This document depicts a chart showing a range of generic drug costs (per tablet and Max. Cost per 30 tablets) and the corresponding “percent mark-up” and “range of profit per 30 tablets.” (*Id.*) According to this table, the percent mark-up increases for inexpensive drugs while the range of profit per 30 tablets remains relatively constant. (*Id.*)

81. Ohio’s Robert Reid testified regarding whether states had to rely upon prices reported in the compendia to adjudicate claims for generic drugs:

Q. Now, here Ohio did not pay prices that were 1,000 percent higher than Abbott’s actual prices, did it?

A. Ohio did not.

Q. So at least in Ohio, Abbott’s alleged misconduct did not ensure its customers of receiving inflated reimbursement; right?

MS. GEOPPINGER: Object to the form. You can answer.

A. I would say yes.

Q. How’s that?

A. How is that?

Q. You would say that it did not ensure that Abbott’s customers were –

A. Well, we didn’t pay attention to AWP and WAC, so, therefore, we don’t – we didn’t pay pharmacies more than what we should have based on our methodology.

Q. So at least in Ohio, these prices did not ensure that Abbott’s customers would receive inflated reimbursement in profits; correct?

MS. GEOPPINGER: Object to the form of the question. You can answer.

A. To the best of my knowledge, that’s true.

Q. It's because the State of Ohio controls what the State of Ohio will pay on claims for Abbott's drugs; correct?

A. Correct.

MS. GEOPPINGER: Object to the form of the question.

A. As with other manufacturers as well.

Q. Go to page 2, Paragraph 3.

A. 3, okay.

Q. The second sentence, it's the fourth line down of that paragraph, it starts on the right with the word "In."

A. "In," I got it.

Q. States, "In furtherance of this scheme, Abbott reported false, fraudulent and inflated drug prices for certain drugs listed in the Paragraph 31 – Paragraphs 31 and 35 below, to several price reporting compendia that the Medicare and Medicaid programs were relied upon to set reimbursement rates for Abbott's customers." See that?

A. Somebody said that. I didn't say it.

Q. Ohio did not rely upon the compendia prices to set reimbursement for Abbott's customers –

A. That's correct.

Q. And no state had to rely upon those prices if they chose not to; correct?

MS. GEOPPINGER: Object to the form of the question.

MR. HENDERSON: Objection.

MS. GEOPPINGER: You can answer.

A. I don't think it was mandatory for any state to rely on compendia prices.

Q. Any state could have done what you did –

A. Or –

Q. – and set a MAC price?

MS. GEOPPINGER: Object to the form of the question. Go ahead. Is that a question?

MR. TORBORG: Yes.

MS. GEOPPINGER: Is the question could they have done that?

MR. TORBORG: Yes.

THE WITNESS: Oh, they could have, yes.

MS. GEOPPINGER: Same objection.

BY MR. TORBORG:

Q: And you managed to do this MAC program and avoid this whole problem all by yourself in Ohio; right?

A. I'm –

MS. GEOPPINGER: Object to the form of the question.

A. As far as I know, I'm the only one that did it.

(12/15/2008 Reid Dep. at 221:21-225:16, Ex. 2.)

82. Tennessee's H. Leo Sullivan testified regarding the importance of MAC pricing:

A. The question, though, that, that boggles my mind, and it did at this time when I interacted with my peers, when they're wringing their hands over issues like this, I'm just --you know, I'm just curious why you don't get out there, find out what the drugs cost, and set the price yourself. You can always MAC things. You can MAC a brand name drug if you want to. But go ahead.

(3/12/2008 Sullivan Dep. at 240:4-12, Ex. 1.)

83. Maine's Judge Walsh testified regarding how Maine reimbursed for physician administered drugs based on acquisition cost:

A. That's incorrect. Physicians – J codes are administered by the provider in the office setting. So typically they are an injection or an infusion and they are drugs that the physician bills the acquisition cost and the visit.

Q. So it is an acquisition cost and you are looking at the invoice then?

A. We certainly can call in the invoice, the invoice can be produced if we request it.

Q. And how -- do you know how the physicians determine acquisition cost?

MS. ST. PETER-GRIFFITH: Object to the form.

A. Physicians don't determine acquisition costs, physicians have invoices that show what they acquire the drugs at, that's -- that's acquisition.

(3/26/2008 Walsh Dep. 110:6-111:1, Ex. 154.)

84. New Jersey's Ed Vaccaro testified regarding how New Jersey reimbursed for physician administered drugs based on acquisition cost:

Q. Okay. And is there a physician claim form that requires the physician to submit its actual acquisition costs or its acquisition costs as it's defined here?

A: The acquisition cost would be reflected as their charge on that claim form.

Q. How is charge defined for a physician?

A. In the case of an injectable?

Q. Yes. In the -- well, in the case of an injectable and inhalation drug.

A. It would be his acquisition cost.

Q. How would it -- how would a physician compute its acquisition cost?

A: Be an invoice.

Q. This is an invoice that the -- that reflects the payment that the physician --

A. Purchased.

Q. -- made for the purchase of the pharmaceutical?

A. The purchase of the injectable, correct.

Q. Okay. Now, if you go -- and your understanding is this is not the same thing as the average wholesale price; correct?

A. Correct.

Q. Okay. Which is consistent with your application of regulations in general that you apply the literal meanings of the regulations; correct?

A: Correct.

(12/3/2008 Vaccaro Dep. 519: 7-520:20, Ex. 80.)

\* \* \*

Q. The actual -- the physicians submitted in their claims the actual acquisition costs for injectables --

A. That is correct.

Q. -- is that correct?

A. That is correct.

Q. And I was unclear in your earlier testimony what they were submitting. Was it the actual -- was it the actual cost that the physicians paid for those drugs?

A. Yes.

Q. Did New Jersey give any guidance to the physicians as to how they should calculate their actual acquisition costs?

A. It was -- it was -- now, I'd have to reference the physician's manual to be sure, okay, but it would be their costs, their invoice costs.

Q. Did you tell them whether or to what extent discounts or rebates should be included if they were not reflected in the invoice?

A. No, I -- again, it was expected it would be their actual cost, whatever that was. The bottom line. If there were discounts or rebates involved, we expected to receive a number that reflected their purchase cost.

(*Id.* at 668:10-669:13.)

85. Delaware Medicaid reimburses pharmacies and other providers that qualify for “special purchasing” such as 340b pricing and Robinson Patman Act purchasers based on actual acquisition costs, which those providers must submit as part of their claim for payment. (12/9/2008 Denmark Dep. at 108:4-112:2, Ex. 22.)

86. DOJ’s expert admits he simply “assumed” for all claims that, if lower compendia prices were reported, payments would have been based on those prices. (Duggan 5/19/09 Dep. at 345:14-16 (Medicaid), Duggan 2/27/09 Dep. at 420:14-16 (Medicare).)

**L. FULs**

87. From 1987 to 2006, the FUL regulation permitted the Government to establish a “federal upper limit” for qualifying generic drugs at 150% of the published price for the least costly therapeutically equivalent product. (Dey SOF at ¶¶ 239, 241.)

88. With the exception of six NDCs, 0007-46138-02, 0074-6138-03, 0074-6138-22, 0074-7138-09, 0074-7924-09, 00074-7972-05 each of the 44 Complaint NDCs in the Abbott case met the criteria for the establishment of a FUL during the relevant time period. (Ex. 158 at 32 n 51) (Expert Report of Steven J. Young) (“The majority of the NDCs in this matter met the requirements to have a FUL calculated, but the CMS did not do so.”).)

89. Although most of the drugs in this case met the regulation’s requirements, CMS sometimes did not establish a FUL for a particular drug, or removed a FUL for a particular drug, because of concerns about the availability of the drug. (Dey SOF at ¶¶ 244-247.)

90. There was no formal guidance for how or when to not set, or to remove, a FUL for a qualifying drug; this review was left to CMS’s discretion. (Dey SOF at ¶ 244.) CMS officials were informally taught by other CMS officials how to exercise their discretion to set FULs manually so as to meet the dual objectives of cost savings and access. (1/24/08 Gaston Dep at 225:16 -226:7, Ex. 34; 5/20/08 Sexton Dep. at 73:14-74:22, Ex. 159.)

91. Moreover, FULs are supposed to be set based on the *lowest* published price, 52 Fed. Reg. 28648 (July 31, 1987), and AWP's were not the lowest of published prices. (3/19/08 Gaston Dep. at 456:10-456:20, Ex. 147; Rox. 56.1 ¶¶ 116-123; 278) Sue Gaston, the CMS employee responsible for setting FULs from April 1991 through February of 2003, testified that CMS “wouldn’t have used AWP” when establishing FULs because “[s]etting a FUL using the AWP wouldn’t achieve the cost savings.” (*Id.* (3/19/08 Gaston Dep. at 458:15-459:7, Ex. 147 ); *see also id.* (5/20/08 Sexton Dep. at 49:13-50:21, 76:20-77:13, Ex. 159) (the CMS employee responsible for setting FULs beginning in 2004 testified that she could not recall ever having set a FUL based on an AWP). So, if there was a FUL in place, published AWP's could *never* influence actual payment of the claim because the FUL was always *lower* than the published AWP.

### III. MEDICARE

#### A. November 25, 1991 Final Rule

92. On June 5, 1991, CMS published a proposed rule relating to Medicare Part B’s payment for drugs administered incident to a physician’s service. The proposed rule stated, “we are proposing that we will instruct all carriers to base payment for drugs on 85% percent of the national average wholesale price of drug (as published in Red Book and similar price listings), but we welcome comments regarding the appropriate discount.” (Ex. 160 (56 Fed. Reg. 25792, 25800) (Abbott Ex. 120).) The proposed rule also stated that “the Red Book and other wholesale price guides substantially overstate the true costs of drugs.” (*Id.*)

93. CMS’s proposal to base Medicare Part B drug payment at 85% of AWP for drugs furnished incident to a physician’s service was not implemented. Instead, HCFA implemented a payment regulation whereby Medicare Part B payment for multiple source drugs and biologicals was calculated as the “lower of the estimated acquisition cost described in paragraph (b) of this

section or the wholesale price that, for this purpose, is defined as the median price for all sources of the generic form of the drug.” (42 C.F.R. § 405.517(c), Ex. 161 (56 Fed. Reg. 59502, 59621)

(Abbott Ex. 1020).) 42 C.F.R. § 405.517(b) provides the following methodology:

Payment for a drug described in paragraph (a) of this section is based on the lower of the estimated acquisition cost or the national average wholesale price of the drug. The estimated acquisition cost is determined based on surveys of the actual invoice prices for the drug. In calculating the estimated acquisition cost of a drug, the carrier may consider factors such as inventory, waste, and spoilage.

(*Id.*) If the providers’ billed charge was lower than the estimated acquisition cost or the average wholesale price, Medicare carriers would pay based on the providers’ billed amount. (Ex. 155 (Abbott Ex. 309).) This payment methodology reimbursement level was effective as of November 25, 1991 and remained in effect until Congress enacted the Balanced Budget Act of 1997. BBA of 1997 set payment for drugs paid under Medicare Part B at “95 percent of the average wholesale price.” (42 U.S.C. § 1395u(o); Pub. L. No. 105-33 § 4556(c), 11 Stat. 251, 463 (1997), Ex. 162 (Abbott Ex. 201).) If the providers’ billed charge was lower than the 95 percent of the average wholesale price, Medicare carriers would pay based on the providers’ billed amount. (Ex. 163 (Abbott Ex. 529).)

94. The preamble to the November 25, 1991 final rule acknowledges that “many drugs could be purchased for considerably less than 85 percent of AWP – particularly multi-source drugs.” (56 Fed. Reg. 59502, 59524, Ex. 164 (Abbott Ex. 301).)

95. In a section titled “Effects of Separate Payment for Drugs,” the preamble to the November 25, 1991 final rule contained the following language:

Under our *final policy*, carriers will be instructed to base payment for drugs on the lower of estimated acquisition cost or the national average wholesale price of the drug *as published in the Red Book and similar price listings*.

(*Id.* at 59615 (emphasis added), Ex. 164 (Abbott Ex. 301 at Page 18).)

96. The preamble to the November 25, 1991 final rule also contained the following language:

f. *Low osmolar contrast media (LOCM)*. Divergent payments exist among carriers for LOCM, also known as non-ionic contrast material, for radiological studies. We will pay separately for LOCM if it is used for patients with specified characteristics under the *standard methodology for payment of drugs generally*. That is, we will base payment on the lower of estimated acquisition cost or the published wholesale price of the drug. The estimated acquisition costs will be determined based on carrier surveys of actual invoice prices paid by physicians.

(*Id.* at 59509 (emphasis added), Ex. 164 (Abbott Ex. 301 at Page 24).)

97. In October 1991, the OIG provided comments to CMS noting that the preamble to the 1991 regulation “uses the term ‘published wholesale price’ while the regulation[’]s text uses the term ‘national average wholesale price.’” (Ex. 165 (HHD816-0025).) OIG stated, “We believe separate terminology may lead to confusion.” (*Id.*)

98. On or around March 14, 1994, the Director of the CMS Office of Payment Policy issued a memorandum to all CMS Regional Administrators that set forth, among other things, how carriers should determine the AWP for purposes of Medicare Part B’s payment for drugs. (Ex. 166 (Abbott Ex. 114).) That memorandum included the following language:

Determination of AWP – To determine AWP, calculate the median price of the generic form of the most frequently administered dosage of the drug as reflected in sources such as the Red Book, Blue Book, or Medispan. . . .

\* \* \*

Additional Costs – Section 405.509 of the regulations permits the carriers to consider additional costs when determining the estimated acquisition costs of a drug. We have been told that for some drugs, notably chemotherapy drugs, physicians may incur additional costs related to the drugs. These costs have been described as overhead costs and include storage, waste, spoilage.

breakage, and handling. Some physicians do not incur costs for handling drugs in their offices because they use a drug dispensing service. In addition to the estimated acquisition costs, consider allowing an additional fee for the overhead of handling or dispensing drugs. However, in no case can the payment for the drug plus a dispensing fee exceed the AWP for the drug.

(*Id.* at HHC903-0914 – 15.)

**B. The Balanced Budget Act of 1997**

99. Section 4456(c) of the Balanced Budget Act of 1997 includes the following provision:

(C) STUDY AND REPORT - - The Secretary of Health and Human Services shall study the effect on the average wholesale price of drugs and biologicals of the amendments made by subsection (a) and shall report to the Committees on Ways and Means and Commerce of the House of Representatives and the Committee on Finance of the Senate the result of such study not later than July 1, 1999.

(Pub. L. No. 105-33, Section 4456(c), 11 Stat. 251, 463 (1997).)

100. To comply with Section 4556(c) of the Balanced Budget Act of 1997, Donna Shalala, Secretary of the Department of Health and Human Services, provided a “Report to Congress on The Average Wholesale Price For Drugs Covered Under Medicare” in 1999. (Ex. 167 (HHC902-0801 – 18).) In her report, Secretary Shalala compared the increase in AWP’s reported by First Databank with inflation. (*Id.* at HHC902-804.) Ms. Shalala report included the following language:

The AWP is not a well-defined concept nor is it regulated in any way. OIG reports that AWP is set by manufacturers as a suggested price and published in various commercial sources. However, it is not truly an average of wholesale prices because very few purchasers actually pay this amount.

\* \* \*

Conclusions are further obfuscated by the OIG finding cited earlier in this report that, as an unregulated, suggested price, typically set

by the manufacturer, the AWP bears no consistent or predictable relationship to the prices actually paid by physicians and suppliers to drug wholesalers in the marketplace.

(*Id.* at HHC902-0803, 0809.)

101. T. Mark Jones provided the following testimony:

Q. Quote, "During that meeting, we were shocked by certain statements made by certain HCFA officials concerning their understanding that the term AWP had never been legislatively or administratively defined by the Federal Government," close quote.

Was that statement made during your September 1995 meeting?

A. I remember it being said that AWP isn't defined. That's how I remember these. I don't remember it being legislatively or administratively defined.

Q. The people who were making that statement, they were the people at HCFA who were responsible for administering the Medicare and Medicaid programs. Correct?

A. To the best of my recollection, I remember it being Sheree Kanner who was the general counsel for HCFA.

Q. You remember it was Ms. Kanner who said that AWP --

A. That's how I remember it, yes.

Q. And as the office of general counsel, you understand that Ms. Kanner was HCFA's lawyer. Correct?

MR. BREEN: Objection to form.

THE WITNESS: Yeah. I guess.

BY MR. COOK: Q. Did you disagree with Ms. Kanner about whether AWP had ever been legislatively or administratively defined by the Federal Government?

A. I don't remember if I had any dialogue with her over it.

Q. Did Mr. Lavine disagree with Ms. Kanner at this meeting?

A. I don't remember it being a big dialogue. I think it was a statement that I remember.

Q. Do you remember anybody at that meeting disagreeing with Ms. Kanner that AWP had never been legislatively or administratively defined by the Federal Government?

A. No.

(3/19/08 Jones Dep. at 551:9-553:8, Ex. 168.)

102. CMS instructed its carriers in its regulations implementing the Balanced Budget Act of 1997 to set payments at 95 percent of the national average wholesale price “as reflected in sources such as the Red Book, Blue Book, or Medispan.” (Ex. 169 (63 Fed. Reg. 58814).) CMS’s regulations stated that “it is clear that the AWP is higher than the amount typically paid for drugs by physicians” and that “significant discounts from AWP are common.” (Ex. 169 (63 Fed. Reg. 58849-50).)

103. And in 2001, GAO publicly announced that the “*term AWP is not defined in law or regulation*, so the manufacturer is free to set AWP at any level, regardless of the actual price paid by purchasers.” (Ex. 170 at 4 (GAO Report, “Medicare Part B Drugs: Program Payments Should Reflect Market Prices”).)

**C. Federal Testimony On The Meaning Of AWP**

104. Numerous federal CMS and OIG officials testified that CMS understood that the term AWP referred to prices published in the drug compendia. For example:

(a) Bruce Vladeck served as the CMS Administrator from 1993-97. Dr.

Vladeck testified regarding how CMS interpreted the term AWP:

Q. And the AWP in that legislation, did you understand that in the same way you understood AWP in the regulation from 1992?

A. Yes.

MS. BROOKER: Objection. Form.

Q. And so that would refer to a published average wholesale price. Correct?

A. That was our understanding of it, yes.

(5/4/07 Vladeck Dep. at 278:18-279:03, Ex. 39.)

(b) Nancy-Ann DeParle served as CMS Administrator from 1997-2000.

(5/18/07 DeParle Dep. at 54:6-7, 55:20-56:1, Ex. 66.) Ms. DeParle testified regarding how CMS interpreted the term AWP:

Q. So this was issued just as Congress was essentially taking out of HCFA's hands the discretion to use some measure other than average wholesale price --

MS. YAVELBERG: Objection to form.

Q. -- to pay for drugs; correct?

A. The BBA specified how drugs were to be reimbursed.

Q. And that was to be reimbursed at 95 percent of the average wholesale price; correct?

A. Yes.

Q. And the agency interpreted that to refer to the prices published in the Red Book and Blue Book; correct?

MS. YAVELBERG: Objection; form.

A. Yes.

(*Id.* at 130:19-12.)

(c) Thomas Scully served as CMS Administrator from May 2001 through January 2004. (5/15/07 Scully Dep. at 97:12-15, 50:8-13, Ex. 64.) Mr. Scully testified regarding how CMS interpreted the term AWP:

Q. And was it your understanding that the, that the AWP that CMS was using as the benchmark for reimbursement was the AWP that was published in the compendia?

A. For the most part, it was my understanding that the standard practice was that 95 percent of AWP was the AWP that was published in the Red Book.

Q. And that's what you understood the law and regulations to require?

A. That's what I understand at the time. At the time, that's what I believe the law and regulations required.

(*Id.* at 105:17-106:06.) Mr. Scully also testified that AWP is "air", "it's nobody's fault, it's a stupid policy." (*Id.* at 195:3-5.) Mr. Scully provided the further testimony:

I don't blame anybody for doing what they did. The government created stupid incentives. But it was an insane policy. And so, understanding it from both sides, I was determined to fix.

(7/13/07 Scully Dep. at 493:14-18, Ex. 65.)

(d) Thomas Scully testified regarding the definition of AWP set forth in the United States' Complaints in the DOJ Actions:

Q. Okay. Now, this was a complaint that was signed the 22<sup>nd</sup> day of August, 2006, and on paragraph 40, in the first sentence, it says, AWP is used to refer to the price at which a pharmaceutical firm or a wholesaler sells a drug to a retail customer, who then administers it to a patient; do you see that?

A. Yes.

Q. That's not what AWP was viewed as, that's not the view of CMS as to what AWP was, is it?

MR. NEAL: Objection as to form.

By MR. ESCOBAR:

Q. Is it?

MR. NEAL: This is not a 30(b)(6), this is not a 30 (b)(6) deposition. You can answer.

A. No, I don't think that's what AWP is commonly considered to be, I think that's an inaccurate description.

Q. In fact, that's a completely inaccurate statement of AWP; right?

MR. NEAL: Objection as to form.

A. I think it's probably a poor description, yes.

Q. Because it's not accurate?

A. Yes.

(7/13/07 Scully Dep. at 709:20-711:02, Ex. 65.)

\* \* \* \* \*

Q. All right. Have you ever used average wholesale price to refer to the price at which a pharmaceutical firm or a wholesaler sells a drug to a retail customer?

A. No.

MR. GOBENA: Object to the form.

Q. Have you ever heard anybody else use AWP to refer to the price of which a pharmaceutical firm or a wholesaler sells a drug to a retail customer?

MR. GOBENA: Object to the form.

A. No.

(*Id.* at 900:16-901:06.)

(e) Kathleen Buto, Director of the Bureau of Policy Development, played a central role in drafting November 25, 1991 final rule. (9/12/07 Buto Dep. at 50:10-52:2, Ex. 171.) Ms. Buto testified regarding what CMS by the use of the terms "national average wholesale price" in the November 25, 1991 final rule:

Q. . . . Is it fair to say, Ms. Buto, that the intent of CMS in drafting this provision with respect to average wholesale price was to refer to the prices that are found in Red Book and similar price listings?

A. Yeah. The intent, though, unfortunately, which was never really achieved, was that was the fallback if the agency couldn't come up with estimated acquisition cost. The agency never really came up with estimated acquisition cost.

Q. There were two possibilities for determining the payment amount, one was estimated acquisition cost. If you were not able to find that for a particular drug then it would be reimbursed under

the intent of your regulations by virtue of the average wholesale price as published in Red Book and similar price listings, correct?

A. Yes. That's certainly the result. . . .

\* \* \* \* \*

Q. But if we used the average wholesale price method it would be based on what was published in the Red Book, correct?

A. Yes. That was made clear later in one of the other documents, that it was based on the published. But in the -- I think in the original description they didn't refer to published.

(*Id.* at 272:3-22, 306:2-81.)

(f) Charles Booth, former Director of CMS's Office of Payment Policy, testified regarding how CMS interpreted the term AWP:

Q. During this time period from 1991 to 1997 what was your understanding of what AWP referred to?

A. AWP was what the manufacturers chose to put in the compendia.

Q. At any time in this time period did you understand AWP to refer to a calculated average of wholesale prices that were charged to physicians or other purchasers of these products?

A. No.

(4/23/07 Booth Dep. at 518:10-18, Ex. 172.)

(g) Robert Niemann, CMS Drug Payment Policy Analyst (Medicare), testified regarding how CMS interpreted the term AWP:

Q. What did you understand Congress to be referring to in Exhibit Abbott 201 when Congress referred to 95 percent of the average wholesale price?

A. I guess -- I don't remember -- I don't remember the content of any conversations I had with Congressional staffers that would inform on the answer to that question, but whatever they had in mind, this instruction here seems to state that same language that we've discussed ad nauseam before now as reflected in sources such as the Red Book, Blue Book or Medispan.

(10/11/07 Niemann Dep. at 366:10-21, Ex. 173.)

(h) Dr. Robert Berenson, Director of the Center for Health Plans and Providers and later as Deputy Administrator from 1998 to 2001, testified regarding how CMS interpreted the term AWP:

Q. In any of your discussions when you worked at HCFA or CMS, did you ever use the term average wholesale price to refer to the price at which a manufacturer sells a drug to a retail customer?

MR. DRAYCOTT: Objection.

THE WITNESS: I have no idea. I can't remember that.

BY MR. MURRAY:

Q. Do you ever remember hearing anyone else use it to mean that?

A. As I said earlier, I think there was a common understanding within the agency that AWP referred to the prices in these compendia and that they deviated from actual acquisition prices and that's how we sort of viewed AWP.

(12/18/07 Berenson Dep. at 72:21-73:3, Ex. 174.)

(i) Robert Vito, Office of the Inspector General, Regional Inspector General, testified regarding his understanding of the term AWP:

Q. . . . During your approximately thirty years at the OIG, have you understood that the term "average wholesale price" referred to prices in the compendia, such as Red Book?

MR. NEAL: Object to the form.

THE WITNESS: I -- I -- I believe that I understood that AWP was reported in books like the Red Book and the Blue Book.

\* \* \*

Q. When you used the term "average wholesale price," did you equate it to the prices that were in Red Book and other price listings?

MR. AZORSKY: Objection to the form.

MR. NEAL: Join the objection.

THE WITNESS: I believe it was listed in the Red Book and the Blue Book, yes.

(6/17/07 Vito Dep. at 135:08-15, 144:6-12, Ex. 175.)

(j) Linda Ragone, Deputy Regional Inspector General for OIG, testified:

Q. Okay. Did you understand Congress to be directing HCFA to pay 95 percent of the published AWP?

MR. DRAYCOTT: Objection.

A. I believe when I read that that—well, I don't—I don't have it in front of me, so I believe that it was supposed to be 95 percent of average wholesale price.

BY MR. COOK: And you understood that to be what is published in Red Book, Blue Book, Medispan, right?

A. That's what I took it to mean.

(4/18/07 Ragone Dep. at 552:1-12, Ex. 176.)

(k) David Tawes, Director of the Medicare and Medicaid Drug Pricing Unit, testified regarding his understanding of AWP:

A. I don't remember any specific conversations about EAC. The conversations would have been just that Medicare is required to pay 95 percent of AWP.

BY MR. TORBORG: And your understanding of that (AWP] relates to what was published in Red Book or other price listings, right?

MR. NEAL: Objection as to form. You can answer.

A. Yes.

(4/24/07 Tawes Dep. at 141:14-142:2, Ex. 177.) Mr. Tawes agreed that the term AWP was well-understood in the industry to mean prices published in the compendia. He disagreed that changing the definition of AWP was a statutory change because there was in fact no statutory definition for AWP. He testified:

Q. Did you believe that the term “average wholesale price” was commonly understood in the industry?

MR. NEAL: Objection as to form.

THE WITNESS: Yes.

BY MR. TORBORG:

Q. And how was it commonly understood in the industry?

MR. NEAL: The same objection.

THE WITNESS: I’m not sure that I knew the exact definition that the industry would use. However, I believe that the industry obviously knew that AWP’s were not based on -- on wholesale prices; that it was simply a -- a price for their products that they wanted to list in compendia.

BY MR. TORBORG:

Q. So it was your understanding that it was commonly understood in the industry that the term “average wholesale price” referred to prices published in pricing compendia such as Red Book or Blue Book?

MR. NEAL: Objection as to form.

THE WITNESS: Yes.

BY MR. TORBORG:

Q. Do you agree with the statement made in this form letter, that changing the definition of average wholesale price away from what was ever in the pricing compendia to something else was a change in Medicare statutes?

MR. NEAL: I’ll object to the form.

THE WITNESS: No.

BY MR. TORBORG:

Q. Why not?

A. Because AWP was never defined in statute.

\* \* \*

Q. But it was you understanding that it was commonly understood in the industry, including by members of HCFA, that AWP referred to prices published in Red Book, Blue Book, and other pricing compendia?

MR. NEAL: The same objection.

THE WITNESS: AWP, yes, people knew that WPs referred to the prices that were published in -- in compendia.

(4/25/07 Tawes Dep. at 481:13-484:5, Ex. 178.)

105. Near the end of fact discovery, after relevant CMS officials repeatedly testified that they understood the term AWP to refer to compendia prices, Defendants once again sought to understand the factual basis for the position and statements made in an DOJ's *amicus* brief, purportedly made "on behalf of the Secretary of Health and Human Services" in "response to the Court's request that the Secretary explain his views on the term 'average wholesale price' (AWP), as reflected in the Medicare Act, see 42 U.S.C. §§ 1395 et seq., and federal regulations." (Dkt. No. 3104). Counsel for Abbott served the United States with deposition requests concerning "CMS's contemporaneous position during 1991-2003 concerning the meaning of AWP in any relevant Medicare or Medicaid statute or regulation," including how CMS "interpreted and applied" the term AWP in the 1991 final rule, the Balanced Budget Act of 1997, and the Medicare Modernization Act of 2003. The DOJ objected to Abbott's 30(b)(6) notice, agreeing only to produce a witness on the different question of how CMS "applied" the term AWP in the 1991 final rule and the Balanced Budget Act of 1997. The witness the DOJ designated on that topic, Don Thompson, refused to provide substantive answers on how the agency interpreted AWP—instead merely reciting that any agency interpretation would be "contained in the rulemaking record." (3/28/08 Thompson Dep. at 131:4-16, 167:3-18, 222:9-223:9, Ex. 179.)

106. Mr. Thompson explained his understanding of the two meanings of AWP as follows:

Q. It's simply are you aware of a common usage of the term average wholesale price by anyone?

MR. DRAYCOTT: Objection.

A. Again, I'm aware of two. There's the kind of regulatory Part B payment policy concept and then I'm aware of prices reflected in the compendia concept.

Q. And I'm just trying to distinguish between the two, the first being a regulatory phrase as used in regulations and used in technical Medicare Part B payment discussions. And am I correct that when you refer to the latter you're referring to the common usage of the term average wholesale price?

MR. DRAYCOTT: Objection.

A. No. I guess I would -- I'm not making a distinction between the kind of common usage definition and the Medicare Part B payment policy. Where I'm drawing the distinction between the Medicare Part B payment policy and common usage definition and the prices reflected in the compendia.

(*Id.* at 119:17-120:17.)

107. Despite Mr. Thompson's testimony regarding the distinction between the Medicare Part B payment methodology plain meaning understanding of AWP and the AWP prices reflected in the compendia, CMS consistently defined AWP in its Program Memoranda, which Mr. Thompson considers part of CMS policy, as "the AWP as reflected in sources such as the Red Book, Blue Book or Medispan." (Ex. 180 (Abbott Ex. 1014); Ex. 181 (Abbott Ex. 1015); Ex. 182 (Abbott Ex. 1006); Ex. 183 (Abbott Ex. 1008); Ex. 184 (Abbott Ex. 1011).)

108. Mr. Thompson further testified that CMS's position is set forth in Federal Register Notices:

A. The agency's position with respect to Medicare Part B drug payment policy is contained in the Federal Register notices. So if I'm being asked to testify as to the agency's position, the agency's position is stated in its rulemaking documents.

(Thompson 3/28/08 Dep. at 128:11-128:16, Ex. 179.) When asked about language in the preamble to the November 25, 1991 final rule, Thompson testified:

Q. Well, tell me what is the purpose of the preamble that's published to the final regulation in the Federal Register?

A. To assist in explaining the agency's rationale for the regulations that are put into the Code of Federal Regulations.

Q. So you would agree with me that if I were looking to determine what the phrase national average wholesale price means, the first place I would look would be to the preamble, correct?

MR. DRAYCOTT: Objection.

A. The first place would be the regulatory language.

Q. Right. But if I look at the regulatory language and want additional information to tease out what precisely that language means, the first place I would look after the regulation is the preamble, correct?

A. Correct. You would look at the preamble in its entirety and then use that to assist you with respect to 405.517.

Q. And in this instance in the preamble the agency states in this sentence that national average wholesale price is referring to the published wholesale price of the drug, correct?

A. The sentence reads "That is, we will base payment on the lower of the estimated actual acquisition cost or the published wholesale price of the drug."

Q. Right.

A. That's what the sentence says. I would agree that that's what the sentence says.

(*Id.* at 153:14-155:2.)

109. HHS employees have repeatedly testified that AWP is not defined or regulated in any way. For example:

(a) Robert Vito, one of the OIG's head auditors in charge of assembling OIG reports on AWP, stated that AWP's could not even be properly audited by the OIG because there

is no regulatory or statutory definition that defines what it is, much less what a manufacturer must do: “I’ve testified before Congress that AWP is not defined, not auditable . . . .” (6/20/2007 Vito Dep. at 399:9-22, Ex. 185.)

(b) Dennis Smith, CMS’s most senior official with respect to Medicaid testified that “[AWP] is not further defined in law or regulation . . . . There is no definition, precise.” (3/27/2008 Smith Dep. at 430: 2-7, Ex. 186.)

(c) In April 2003, the OIG released its Compliance Program Guidance for Pharmaceutical Manufacturers. The compliance guidance was “intended to assist [pharmaceutical manufacturers] in developing and implementing internal controls and procedures that promote adherence to applicable statutes, regulations, and requirements of the federal health care programs . . . .” The guidelines explicitly made clear that they were not intended as a rule and that they did not create any “new law or legal obligations.” (Ex. 187 (2003 OIG Compliance Program Guidance) (Abbott Ex. 149).)

110. Medicare carriers also provided testimony that they understood the term AWP to refer to prices published in the drug compendia. For example:

(a) Rena Clark testified on behalf of Wisconsin Physician Services (“WPS”), a Medicare carrier. Ms. Clark testified:

Q. Did CMS direct WPS where to look to obtain average wholesale price?

A. Yes.

Q. Where did CMS direct you to look?

A. There were a couple sources. The one we used most of the time was the Red Book drug topics.

Q. In your work at WPS has the term average wholesale price been synonymous with what – the prices that would be contained in the Red Book or other price listings?

MR. HENDERSON: Objection.

THE WITNESS: Yes.

BY MR. TORBORG:

Q. When you thought of AWP, you thought of Red Book; is that fair to say?

MR. HENDERSON: Objection.

THE WITNESS: That's true.

(2/8/08 Clark Dep. at 67:12-68:4, Ex. 188.)

\* \* \* \* \*

Q. So if I understand correctly, in order for you to be able to use an AWP price, it has to specifically come from Red Book?

A. It doesn't have to specifically come from Red Book, but it has to specifically come from a published compendia. And a published compendia is something that's published that -- I guess it's not the manufacturer saying, we've raised the price; this is what our new Red Book amount is. It comes from the Red Book publication or Blue Book or Medispan or whatever.

Q. So if someone from Abbott had called you up and said, Ms. Clark, the AWP for Vancomycin, for example, should be \$5, instead of what it was recorded in Red Book, could you use that?

A. No.

Q. And why is that?

A. Because it would not have been a published source.

(*Id.* at 125:3-21.)

\* \* \* \* \*

Q. Okay. Is it your understanding that the law required that a carrier such as WPS use AWP prices found in published sources such as Red Book, Blue Book, or Medispan?

A. Yes.

(*Id.* at 160:4-8.)

(b) Robin Kreush Stone testified on behalf of Palmetto, a Medicare carrier.

Ms. Stone testified :

A. AWP was always based off of the information published in the drug compendia sources, such as Red Book or and/or Medispan.

(2/28/08 Stone Dep. at 84:1-3, Ex. 189.)

\* \* \* \* \*

Q. Ms. Stone, in calculating drug payments, did you use the compendia because you thought it reflected the prices at which providers were purchasing drugs? Or because you were directed to do so by CMS?

A. Because I was directed to do so by CMS.

Q. Is it fair to say that over the last 30 years, you have been intimately involved in calculating drug payments made by Medicare?

A. Can you repeat that again, please.

Q. Is it fair to say that over the last 30 years, you have been intimately involved in calculating drug payments for Medicare Part B?

A. No.

Q. Would it be fair to say you have been so involved in the last 20 years?

A. Yes.

Q. Based upon that experience, do you believe it's well-established in the industry that the term "average wholesale price" refers to pricing contained in the drug compendia?

A. Can you repeat that, please.

Q. From your experience, do you believe it's well-established that the term "average wholesale price" refers to pricing contained in the drug compendia?

MR. HENDERSON: Objection to the form.

A. Can you say that one more time.

Q. Sure. From your experience, is it well- established that the term “average wholesale price” refers to drug prices in the drug compendia?

A. Yes.

(2/29/08 Stone Dep. at 490:5-491:15, Ex. 190.)

(c) Jean Veal testified on behalf of First Coast Service, a Medicare carrier.

Mr. Veal testified:

Q. Is this how First Coast was directed to get the AWP when calculating payment for drugs, as published in the Red Book or similar price listings?

MR. LAVINE: Object to the form.

A. I don't know if we were instructed to use Red Book, but I think -- I don't know when this was published. Looks like 1995. But, I mean, it does look like these were instructions. I mean, I don't recall ever seeing this, but it does look like that was the instructions.

Q. Did First Coast use the term “average wholesale price” synonymous with the prices which are listed in the Red Book?

MR. LAVINE: Object to form.

A. Did we -- say that again, please.

Q. Did First Coast use the term “average wholesale price” synonymous with the prices which are referenced in the Red Book or other similar compendia?

A. I mean --

MR. LAVINE: Object to form.

A. I mean, I imagine we used the term “average wholesale price,” but I don't -- I mean -- and I know there's average wholesale prices in the Red Book, but I think there's other prices in the Red Book too. I mean, I don't really understanding what you're asking.

Q. If you wanted to find an average wholesale price in your work at First Coast, you would go to the Red Book?

A. Yes.

Q. Is it your understanding that the law required First Coast to use the AWP's found in the Red Book?

MR. LAVINE: Object to form.

A. No. I mean, we weren't required to use the Red Book.

Q. What else could you have used?

A. I think the -- like this says, you could use Red Book and similar price listings. I think some of the other change requests that came out said mentioned Blue Book.

Q. Medi-Span?

A. Medi-Span.

Q. But you always believed you needed to use one of the published compendia?

A. Yes.

(3/25/08 Veal Dep. at 52:2-54:4, Ex. 191.)

(d) Paula Walker testified on behalf of Cigna, a Medicare carrier. Ms. Walker testified:

Q. In the time that you've been at Cigna, is it fair to say that average wholesale price has largely been synonymous with the prices that you would find in the Red Book?

MR. HENDERSON: Objection.

THE WITNESS: I'm not sure what you mean by that.

BY MR. HALE:

Q. Well, when you think of average wholesale price, is it fair to say that you automatically think of what is contained in the Red Book?

A. Yes.

7 MR. HENDERSON: Objection.

(3/12/08 Walker Dep. at 60:16-61:6, Ex. 192.)¶

111. The carriers and DMERCs had discretion to include or exclude certain products in arrays. (See Dkt. No. 6189 ¶¶ 144-46.)

**D. Failed Attempts To Base Part B Payments On Actual Acquisition Cost**

112. In October 1991, the OIG provided comments to CMS on its proposal to pay providers at AWP. OIG suggested to CMS to require providers to bill the “lower of AWP for the specific drug used or the actual invoice price of the drug.” (Ex. 165 (HHD816-0025-27).)

113. Kathleen Buto, the official primarily in charge of promulgating the 1991 regulation testified:

Q. HCFA was well aware of the fact that published prices -- AWP in this case -- were not a reliable indicator of acquisition cost, correct?

MR. DRAYCOTT: Objection. You can answer.

A. HCFA had repeatedly tried to move away from the published AWP to a better method of computing actual acquisition costs. So we were aware that AWP was not a good basis.

Q. And in your personal view what stopped HCFA from succeeded in that effort?

MR. DRAYCOTT: Objection. You can answer.

A. It was probably two or three things. Politics, so a lot of concern on the part of physician groups, particularly oncologists, that, you know, they preferred the current AWP-based system for a number of reasons, didn't want to go to the burdensome and intrusive practice of having their acquisition cost collected by the agency. The lack of -- except for the OIG studies, the lack of good data that the agency could bring forward to show the extent. And concern broadly across a variety of groups that a change would impede access to important treatment. So it was a number of things and -- there's also an underlying concern of government getting into much more regulated pricing. And this would be a first step toward doing that.

(9/13/2007 Buto Dep. at 362:4-363:12, Ex. 36.)

114. CMS again considered paying acquisition cost rather than AWP in 1995 when Robert Neimann drafted proposed regulations to pay based on Actual Acquisition Cost (“AAC”). (Ex. 193 (Abbott Ex. 314).) According to this proposal:

There are numerous accounts of prices for drugs charged to the Medicare program in excess of the true marketplace and that suppliers who bill Medicare receive discounts below the manufacturers’ published average wholesale prices. In effect, the published “average” wholesale price is not the average price actually charged to wholesale customers. In order that the program can obtain the advantage of these discounts, we are adding the AAC to the drug payment methodology.

(*Id.* at 3.) CMS never proposed a regulation to implement this proposal. (9/14/07 Niemann Dep. at 277:4-280:1, Ex. 210.)

115. In 1997 and 1998 the Executive Branch proposed legislation that would have changed the Medicare payment system to pay based on acquisition cost rather than AWP. (Ex. 194 (Abbott Ex. 213).) A letter from Secretary Shalala to Tom Bliley, Chairman of the Commerce Committee discusses the Executive Branch’s attempts to move to an acquisition cost reimbursement system.

Because the estimated acquisition cost approach has proved unworkable, in 1997, the President proposed legislation to pay physicians their actual acquisition costs. Physicians would tell Medicare what they pay for drugs and be reimbursed that amount, rather than the Administration developing an estimate of acquisition costs and basing payment on the estimate. Unfortunately, Congress did not adopt the Administration’s proposal.

Indeed the HHS Inspector General found payments based on average wholesale price data to be 11 to 900 percent greater than the prices available to the physician community. Therefore, in 1998, the President again proposed paying physicians their actual acquisition cost to ‘ensure that doctors are reimbursed no more, and no less, than the price they themselves pay for the medicines they give Medicare patients.’”

116. In a December 1997 radio address, President Clinton urged Congress to adopt the proposed legislation. According to President Clinton, providers who were being reimbursed at AWP were “paying just one tenth” of that to purchase some drugs. (Ex. 195 (Abbott Ex. 55).) President Clinton remarked that AWP spreads of up to 1000% weren’t “even illegal; *they’re just embedded in the practices of the system.*” (*Id.* emphasis added.)

117. According to Bruce Vladeck, CMS was “not fooled into believing that it was paying actual acquisition cost.” (6/1/2007 Vladeck Dep. at 382:7-16, Ex. 196.) Mr. Vladeck explained further:

Q. And so, it is fair to say that during the time you were the administrator of HCFA, the agency did not choose to change the manner in which it reimbursed Medicare Part B drugs?

MS. BROOKER: Objection. Form.

A. I would -- I would frankly personally object to that characterization because I had a growing feeling -- again, I would put this in a period probably beginning about 1995 through the time I left the government -- of frustration that we were significantly overpaying for Part B drugs, and that because of some combination, frankly, of political and legal constraints, we were unable to change it. Again, whether that was a matter of law or a matter of political judgment, whether I was clear then, I’m not clear now, but it was certainly a source of very great frustration to me that we continued to pay what I believed was excessive amounts for the drugs.

Q. And so, “choose” was a bad choice of words?

A. Yes.

Q. Okay. Did not, in fact, change the way in which it reimbursed it, for several reasons?

MS. BROOKER: Objection. Form.

A. Those methods were not, in fact, changed until 2004, I believe.

Q. You indicated that political considerations were one of the bases -- let me rephrase that. You indicated the political pressures

were one of the reasons why the methodology was not changed.  
Correct?

A. I did, yes. That's correct.

(5/4/2007 Vladeck Dep. at 189:10-190:22, Ex. 39.)

**E. Medicare's Rejection Of The DOJ AWP's**

118. On May 31, 2000, HHS Secretary Shalala wrote to Tom Bliley, Chairman of the Commerce Committee, responding a letter Mr. Bliley sent on May 5, 2000 concerning Medicare Part B's payment for drugs. (Ex. 194 (Abbott Ex. 213).) Ms. Shalala's letter included the following statements:

- “We have closely monitored the investigations of drug pricing conducted by the Department of Justice, the HHS Inspector General, and the State Medicaid Fraud Control Units. Let me assure you that share your concern about the significant discrepancies between the prices that Medicare must pay by law and the significantly lower prices at which physicians may obtain these drugs.”
- “Because the estimated acquisition cost approach had proved unworkable, in 1997, the President proposed legislation to pay physicians their actual acquisition costs. Physicians would tell Medicare what they pay for drugs and be reimbursed that amount, rather than the Administration developing an estimate of acquisition costs and basing payment on the estimate. Unfortunately, Congress did not adopt the Administration's proposal. Instead, the Balanced Budget Act reduced Medicare payment for covered drugs from 100 percent to 95 percent of average wholesale price. This recaptures only a fraction of the excessive Medicare payment amounts because, until recently, available average wholesale price data did not correlate to actual wholesale prices for certain Medicare-covered drugs.”
- “Indeed, the HHS Inspector General found payments based on average wholesale price data to be 11 to 900 percent greater than the prices available to the physician community. Therefore, in 1998, the President again proposed paying physicians their actual acquisition cost to ‘ensure that doctors are reimbursed no more, and no less, than the price they themselves pay for the medicines they give Medicare patients.’ However, no Congressional action was taken.”
- “**Current Activity:** We are now moving administratively to take advantage of the newly available, more accurate data on average wholesale prices developed for Medicaid as a result of Department of Justice investigations. These data are from catalogs of drug wholesalers, which the Department of Justice says account for a significant portion of the wholesale market. . . . To obtain the benefits of this new information for Medicare right away, we will provide to the insurance companies

that, by law, Medicare must contract with to pay Part B claims (known as “carriers”) the average of the wholesale catalog prices, just as has been calculated by First Data Bank. In June, we will send this information to Medicare carriers so they can use it when they determine average wholesale prices for their next quarterly update of Medicare drug allowances, which will become effective on October 1, 2000. According to the HHS General Counsel, this is the most immediate action we can take without undergoing the formal rule-making process.”

(*Id.*)

119. In or around May of 2000, CMS Deputy Administrator Michael M. Hash drafted a memorandum to HHS Deputy Secretary Kevin Thurm regarding the DOJ AWP. (Ex. 197 (HHD340-0031-34.)) The United States, asserting the deliberative process privilege, produced only a redacted version of this document and only then after the close of fact discovery.<sup>3</sup> The document includes the following statement:

- “The Health Care Financing Administration (HCFA) is moving ahead to implement revisions to Medicare payments for drugs using new average wholesale prices compiled by the Department of Justice (DOJ). The purpose of this memo is to update you regarding our progress.”
- “*Finally, we also have received a revised opinion from [Office of General Counsel] indicating that HCFA can require carriers to use the DOJ data, even without rule making.* This is because the data is characterized by DOJ as more accurately reflecting average wholesale prices.”

(*Id.*) (emphasis in original). When counsel for Abbott asked the Government to produce a copy of the original or revised legal opinions referenced in this document, the DOJ stated: “Mr. Cook has inquired about an OGC opinion concerning whether CMS could use an alternate source of AWP. to determine payment amounts for drugs. As we previously advised Mr. Cook, we have been unable to locate any OGC document containing this opinion and, based on our inquiries,

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<sup>3</sup> Abbott has asked this Court to force the United States to produce a fully unredacted version of this and other documents withheld under the deliberative process privilege. (See Dkt. No. 6260.)

now believe that the referenced opinion was conveyed orally by OGC staff. (Ex. 198 (3/13/09 Ltr. from J. Draycott to D. Torborg, et al.).)

120. On or around May 18, 2000 CMS Deputy Administrator Michael M. Hash drafted a memorandum to HHS Deputy Secretary Kevin Thurm regarding the DOJ AWP. (Ex. 199 (HHC902-214-44.)) The memorandum includes the following statements:

- **“Issue** We have been considering options for using the alternative average wholesale price (AWP) data provided by DOJ. While we believe that Medicare overpays for the drugs identified by DOJ we also must assure continued beneficiary access to these drugs Per your request we have met with physician and provider groups who furnish Medicare beneficiaries with the drugs on the DOJ list and conducted some impact analyses dilemma arises from the fact that delivery systems have developed around overpriced drugs Reductions in the reimbursement particularly in the magnitude contemplated by the DOJ could disrupt these systems of care. . . .”
- **Background** We recently met with organizations representing oncologists urologists the end-stage renal disease community hemophilia suppliers and suppliers of asthma equipment/drugs and home infusion therapy to discuss their concerns about our use of the DOJ alternative AWP data as basis for determining Medicare’s outpatient drug allowances which are currently based on 95 percent of the AWP. . . .
- These organizations argued that 1) a high profit margin on drugs is necessary to cross-subsidize costs that are underfunded, such as drug administration; 2) beneficiaries would have limited access, as they would possibly have to receive care in more costly less convenient settings; 3) quality of care could deteriorate since, the DOJ list does not cover all drugs and there would be substitution of potentially less effective drugs for which the inflated payment could still be obtained; 4) there is insufficient time and information to successfully implement the change, and the policy was announced without adequate comment from stakeholders -- transition period was seen as critical; and 5) and in exploring an option to pay for drugs based on acquisition costs there was view that acquisition costs should include an adjustment for spillage and additional paperwork and there should not be national limit such as the median actual acquisition costs in Medicare in prior year.”
- “While some of the arguments raised by these organizations appear to have merit, we do not think it is clear in every case made that Medicare payment is inadequate to cover drug administration costs, and that access and quality of care would suffer if we implement the DOJ data. Also, we can not lose sight of the fact that lower drug payments would result in lower cost-sharing and Part premiums for beneficiaries. We continue to believe that Medicare payment for

outpatient drugs is excessive, and that our payment systems should be calibrated to pay correctly for covered drugs and for delivery of those drugs.”

(*Id.*) The Government withheld this document under the deliberative process privilege until the Court ordered its production on November 5, 2008 after an *in camera* review.

121. On or around June 14, 2000, CMS’s Robert Berenson, Director of the Center for Health Plans and Providers, sent a decision memorandum to the CMS Administrator with the subject heading, “Medicare Average Wholesale Price (AWP) for Drug Pricing—**DECISION.**” (Ex. 200 (HHD340-0001-04).) The United States, asserting the deliberative process privilege, produced only a redacted version of this document and only then after the close of fact discovery.

122. On July 28, 2000, 89 members of Congress wrote to Secretary Shalala relating to the DOJ AWP. (Ex. 201 (Abbott Ex. 220).) The Congressional members expressed their concern that “a recent administrative initiative by the Department of Health and Human Services may put Medicare beneficiaries with cancer unnecessarily at risk by denying adequate reimbursement for essential drug therapy.” (*Id.*) They also noted that the term AWP is “a term widely understood and indeed defined by [HHS] manuals to reference amounts reflected in specified publications.” (*Id.*) The Members stated that the “new policy does not take into account the fact that oncologists are chronically underpaid for their drug administrative services in treating cancer patients, a fact that is widely recognized.” (*Id.*) The Congressional members further stated:

It is disturbing that the Department would now seek to circumvent those congressional actions by redefining AWP. We see no basis for such an action in any of our previous legislation, and certainly the Department’s unilateral declaration of a new definition of AWP, with no regulatory process, is inappropriate.

(*Id.*)

123. On September 8, 2000, CMS issued a Program Memorandum, number AB-00-86, titled “An Additional Source of Average Wholesale Price Data in Pricing Drugs and Biologicals Covered by the Medicare Program.” (Ex. 202 (Abbott Ex. 138).) Program Memorandum AB-00-86 provided alternative sources of average wholesale price data for approximately 400 NDCs, including many of the drugs at issue in the DOJ Actions. The Program Memorandum included the statement: “You are to consider these alternative wholesale prices as another source in determining your January, 2001 quarterly update for the 32 drugs (Attachment 1), as per PM AB 99-63.” (*Id.*) CMS did not require the Medicare carriers to use the DOJ AWP in pricing drugs.

124. Ms. DeParle served as the CMS Administrator at the time the DOJ AWP were introduced. Ms. DeParle testified that the “DOJ AWP” effort was a “new policy.” (5/18/2007 DeParle Dep. at 290:13-292:2, Ex. 66.)

125. On November 17, 2000, CMS issued Program Memorandum, number AB-00-115 titled “Source of Average Wholesale Price Data in Pricing Drugs and Biologicals Covered by the Medicare Program” that superseded Program Memorandum AB-00-86. (Ex. 203 (Abbott Ex. 221).) Program Memorandum AB-00-115 included the following statements:

This is to notify you that you should NOT use the Department of Justice (DOJ) data attached to PM AB-00-86 in your next update of Medicare payment allowances for drugs and biologicals. Instead, until further notice, you should delay use of this new source of average wholesale price (AWP) and use the AWP data from your usual source.

While we continue to believe that the AWP reported in the usual commercially available sources are inaccurate and inflated above the true wholesale prices charged in the marketplace, congressional action may preclude the use of this alternative source. To avoid the disruption that would result from a decrease in payment allowances followed by an immediate increase due to final congressional action, we are deferring the use of the DOJ AWP data until further notice.

(*Id.*)

126. On December 21, 2000, Congress enacted the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (“2000 Act”) which required prohibited DHHS from “directly or indirectly decreas[ing] the rates of reimbursement. under the current Medicare payment methodology . . until such time as the Secretary has reviewed the report.” (Pub. L. No. 106-554, § 429(c).)

127. Ms. DeParle, the CMS Administrator, testified that Congress precluded the use of the DOJ AWP:

Q. In the second paragraph it says that Congressional action may preclude the use of this alternative source of data. Did Congressional action preclude the use of the DOJ data?

A. I believe it did.

Q. And do you recall having any conversations with Congress about why Congress took that action?

MS. YAVELBERG: Objection; form.

A. No.

Q. Do you know why Congress took that action?

A. No.

(5/18/2007 DeParle at Dep. 317:2-15, Ex. 66.)

128. In May 2003, HHS proposed a rule titled “Revisions to Average Wholesale Price Methodology” (Ex. 204 (67 Fed. Reg. 74126).) According to the Federal Register, the “rule would propose revisions to the source and methodology for determining the average wholesale price (AWP) of drugs covered by Medicare incident to a physician’s service.” (67 Fed. Reg. 74132-33.). The HHS further stated: “We anticipate significant savings for the program and beneficiaries from using the revised definition of AWP.” (*Id.*)

**F. How CMS Interprets AWP Today**

129. In 2003, Congress passed the Medicare Modernization Act, which replaced the AWP methodology of payment for most drugs covered by Part B with an new paradigm, Average Sales Price (“ASP”). Congress required drug companies to report ASP pricing directly to the government. (42 U.S.C. § 1395w-3a(f).)

130. The Medicare Modernization Act did not change the payment basis for certain products, including vaccines and “infusion drugs” administered through durable medical equipment. (42 U.S.C. § 1395u(o)(1)(A)(iv), Ex. 205 (Abbott Ex. 194). Congress maintained payment for vaccines and infusion drugs administered through durable medical equipment at 95% of AWP. (*Id.*) This payment methodology for vaccines and infusion drugs remains in effect today.

131. Despite access to ASP, CMS uses the AWP published in the compendia to determine payments for vaccines and infusion drugs administered through durable medical equipment. Current CMS official Elizabeth Richter testified regarding how CMS determines payment amounts for vaccines and infusion drugs administered through durable medical equipment:

Q. Currently is the agency undertaking any effort to determine what the average price is at which wholesalers are selling drugs to their customers other than by looking it up in compendia?

MR. DRAYCOTT: Objection. You can answer.

A. Not to my knowledge, no.

Q. So do you understand today to be the statutory command to pay average wholesale price to be satisfied by looking it up in the compendia?

MR. DRAYCOTT: Objection.

A. Yes.

(12/7/2007 Richter Dep. at 69:6-19, Ex. 206.)

132. John Warren serves as the current director of the CMS division that sets payment policies for Part B drugs. (11/06/2007 Warren Dep. at 131:16-18, Ex. 207.) Mr. Warren testified regarding how CMS determines payment amounts for vaccines and infusion drugs administered through durable medical equipment:

Q. Mr. Warren, for infusion drugs are you paying, currently, 95 percent of the average price at which wholesalers sell drugs to their customers, including physicians and pharmacies?

A. We pay 95 percent of the average wholesale price that's published in the Red Book compendium.

(*Id.* at 122:12-18.) According to Mr. Warren, CMS makes no effort to look at ASP for infusion drugs:

Q. And we've already determined that when you implement the statute you look to published numbers, correct?

A. Correct.

Q. You don't look to the ASP, correct?

A. Correct.

Q. You don't seek to determine what the price is that pharmaceutical firms and wholesalers are selling drugs to retail customers, correct?

A. Right.

(*Id.* at 140:5-15.)

133. Mr. Warren testified regarding whether CMS changed its practice after the Court found that AWP should be interpreted in accord with its plain meaning.

Q. Did your division change in any way the manner in which it administered the Medicare program after Judge Saris issued her opinion?

A. We did not.

Q. And so after Judge Saris issued her opinion you continued to pay based upon, as I understand it, published AWP, correct?

A. That is correct.

(*Id.* at 132:3-10.)

**G. Cross-Subsidization**

134. Kathleen Buto, Director of the Bureau of Policy Development when HHS enacted the November 25, 1991 final rule, testified regarding why CMS rejected the initial proposal to use 85% of AWP:

Q. ...Was there any connection between the removal of the 15 percent discount on AWP to concerns about shortfalls in administrative payments and the need to cover other costs associated with the administration of drugs?

A. I'm looking at -- if you'd give me a couple seconds here, I'm looking at the response. Because I don't recall that that was the reason. But let me just look and see what we said in response to that comment. (Reading). It looks to me as if we dodged the question. In other words, they didn't respond one way or the other to whether that was at a reason for going to the alternative methodology. And I'm sure we discussed it. As a general matter, not related per se to this issue, the government doesn't like to pay for some things under one mechanism that was intended for one use and sort of overpay there in order to compensate for other costs. In reality it happens. It looks to me as if what we decided to do is avoid that whole issue, but try to say, okay, here's a compromise approach that we think will address general concerns about the 85 percent but also get us where we want to go, which is to pay accurately for drugs that Medicare is paying for. And that would be the survey approach that the carriers would use and the estimated acquisition cost or the actual acquisition cost.

(9/13/2007 Buto Dep. at 308:3-309:10, Ex. 36.)

135. Ms. Buto testified regarding a question from a Carrier Medical Director on whether physicians were permitted to make a profit from Medicare Part B relating to the administration of drugs:

Q. What was the answer to Mr. Deutsch's question about whether physician is permitted to profit on the resale of the drug or biological which he administers?

A. We didn't answer the question.

Q. Didn't answer the question?

A. Did not answer the question.

Q. Did you deliberately not answer the question at the time or --

A. We deliberately stuck to the payment methodology and did not address the question directly. I think that's pretty clear.

Q. And do you know why you did not answer the question directly?

A. I don't know. But often when you don't want to answer a question directly you stick strictly to the methodology and explain what it is you do do and let people draw other conclusions. But we clearly did not address that directly.

Q. Could I read your response as stating they could profit because the carriers are reimbursing based upon average wholesale price and that was the policy?

A. What was your -- you're asking me if you could have read my response that way?

Q. Yeah. I'm trying to understand your response to the extent you did answer the question.

A. But I clearly didn't answer the question in the response. And I think -- you know, we also didn't say no they can't profit. We just didn't answer the question.

Q. Was that a sensitive issue at the time?

A. I think government regulators don't like to talk about where there's profit or not profit. Even in the DRG system, the hospital system, the idea is Medicare will pay a flat amount per admission and if the hospital can produce the service for less they can keep the difference, but it's not called profit. It's called efficiency. So there's sort of an avoidance of the notion of profit. You know, again, the bedrock principles are pay fairly and in a sense try not to overregulate and let market forces sort of --

(9/12/2007 Buto Dep. at 239:22-241:22, Ex. 171.)

136. On February 16, 1995, in an final rule related to Medicare Coverage of Prescription Drugs Used in Immunosuppressive Therapy, CMS made the following comment regarding Medicare Part B's payment for drugs:

*Comment:* One organization suggested that our payment policy cover not only the costs of drugs, but also pharmaceutical care services. The organization explained that in addition to traditional drug distribution services, contemporary pharmaceutical services include clinical functions that ensure the safe and effective use of drug therapy. Examples of these functions, which were characterized by the commenter as "pharmacy" services, are providing patient education, assessing patient compliance, and monitoring for therapeutic effectiveness and adverse effects.

*Response:* Payment for functions furnished by pharmacists is included in the amount that Medicare pays for the drugs.

(Ex. 208, 60 Fed. Reg. 8951, 8953)

137. Thomas Scully recognized the "need, both politically and substantively" to allow for cross-subsidization relating to Medicare Part B's payment for drugs. Mr. Scully testified:

A. It is a legitimate concern for providers that the reimbursement was going to go down on the drug side. Yes. As I discussed earlier with the RUC, there was a general awareness that because oncologists in particular and rheumatologists and others had done so well compensation-wise, I mean the average oncologist salary was probably going up -- income, 25 to 30 percent all during the '90s because of this drug churn, there had probably been subconsciously in the RUC and other mechanism in Medicare an effort to kind of say, they are making so much money on drugs, why do we keep paying them money on practice expenses. So if you're going to take the money away from drugs, at least they would look at other side as a matter of equity, which we tried to say we were willing to do here.

(5/15/2007 Scully Dep. at 228:16-229:9 -29, Ex. 64.)

Q. Because as you state here at least in some cases they are probably correct about the need for cross-subsidization, correct?

A. Yes. As I said, the issue was whether it's 50 million or 100 million versus clearly not a one for one, but there was clearly some

need, both politically and substantively to put some money back into practice expenses.

(*Id.* at 315:1-8..)

138. In 1998, Eli's Home Care Week, a trade publication, published an article regarding Medicare Part B drug payment. (Ex. 209 (Abbott Ex. 54).) The article reported that the 1998 budget gave HCFA the authority to develop a dispensing fee for drugs. Alan Parver, an attorney, is quoted in the article as stating: "It's unclear to me how, if an entity is paid its acquisition cost for a drug, it could possibly provide any services. In the infusion area, that would probably make it very difficult for a pharmacy to provide any services." (*Id.*) Tim Redmon, from the National Community Pharmacists Association, was quoted as stating the following:

In the past, Redmon claims, "Medicare officials would argue that the service component was 'built into the fee schedule' for prescription drugs. Now that this component may be removed, Medicare's insistence that it 'won't pay for services' means that providers are left unable to service beneficiaries."

(*Id.*)

139. OIG's Robert Vito testified regarding Medicare Part B's payment for drugs:

Q. Do you recall conversations that you were involved in where HCFA acknowledged that respiratory [and] infusion drug providers relied upon reimbursement rates for drugs to cover services?

MR. DRAYCOTT: Objection, you can answer to the extent it doesn't reveal the contents of communications and deliberations occurring at entrance or exit conferences with CMS.

THE WITNESS: Yes.

\* \* \*

Q. And do you recall having the conversations at the exit and entrance conversation, at those meetings?

A. Yes.

Q. Can you tell me about those discussions?

MR. DRAYCOTT: Objection. I instruct you not to answer to the extent it would reveal the communications and deliberations that occurred at those exit and entrance conferences.

BY MR. TORBORG: Because of that, are you accepting the instruction not to answer?

A. Yes, sir.

(2/5/08 Vito Dep. at 652:12-21, 654:2-15, Ex. 185.)

140. In 2002, the National Alliance for Infusion Therapy/National Home Infusion Association sent a written statement to Congress. (Ex. 211 (Abbott Ex. 18).) That statement included the following comments:

- “Providers and suppliers of infusion drug therapies in the home setting are not paid separately by Medicare for the critical services and practice expenses described above. Medicare does not have a separate benefit for infusion therapy, but instead, infusion drugs provided in the home setting are covered exclusively under Medicare’s benefit for durable medical equipment. The only items that are explicitly covered and reimbursed under this limited benefit are the drugs, equipment and supplies. Unlike other health care professionals who administer infusion and injectable drugs currently covered under Medicare Part B, providers and suppliers of home infusion drug therapies do not have a mechanism under Medicare that provides them with reimbursement for the services and facilities necessary to provide these therapies.”
- “This is an extremely important point for policymakers to consider as they seek to reform outpatient drug reimbursement. Since the Medicare program does not explicitly reimburse pharmacists for their practice expenses and professional services (including such home infusion services as compounding), pharmacists currently are “paid” for these costs and functions primarily through reimbursement drugs. Similarly, Medicare does not explicitly pay for nursing services provided by infusion therapy providers. A nurse performs many functions, including patient screening and assessment, patient training regarding administration of the pharmaceuticals and general monitoring of the patient’s health status. To the extent that Medicare reimburses for such services, it is largely through the drug payment. As explained in greater detail below, reductions in drug payments must be accompanied by a contemporaneous re-allocation of payment for these necessary professional services. If drug payments are reduced drastically without such a re-allocation, Medicare beneficiaries will

not be able to receive home infusion drug therapy because the costs of therapy will exceed by a large margin the available reimbursement for the therapy.

\* \* \*

- “For the reasons stated above, at the present time the drug payments for infusion therapy subsidize other functions that the Medicare payment methodologies do not reflect appropriately. The costs of these services and functions far outweigh the costs of the drug product, but these costs are clearly lower than the charges that would be incurred if the patient received treatment in an alternate setting. For home infusion drug therapy, the drug payment is the only available payment mechanism for the services that are essential to providing good quality care. The long-standing use of AWP to determine reimbursement has masked the failure of Medicare and Medicaid payment policies to define and account for the service component.”
- “If changes to the methodology used to calculate drug reimbursement result in substantially reduced drug payments, without corresponding changes to ensure adequate reimbursement for the service component of providing infusion therapies, the end result will virtually guarantee an inability of providers to continue to provide these services. Without the availability of home infusion services, Medicare beneficiaries will be treated in more costly settings.”

141. When asked for his understanding of why Congress retained the 95% of AWP methodology for vaccines and infusion drugs administered through durable medical equipment, Tom Scully, the Former CMS Administrator, testified:

Q. And so at least for the drugs that are subject to this carveout in the home infusion setting, Congress has kept the reimbursement of those drugs at 95 percent of AWP as of --

A. As of October 2003.

Q. That's correct, isn't it?

A. I guess it is. That's what the statute says. Another piece of sausage. I have just forgotten that we did that, to be honest with you, which I assume is why they don't have a dispensing fee for anything but respiratory drugs, because they didn't do that for respiratory drugs.

Q. So it would appear that Congress, at least for these drugs and in that setting of home infusion, has determined to continue to subsidize the provision of the services by overpaying for the drugs, correct?

MR. GOBENA: Object to the form. The legislation speaks for itself.

MR. BREEN: Objection to the form.

BY MR. DALY:

Q. You can go ahead.

A. Yes. I was surprised to see this. I forgot we did it. It was certainly never discussed by members. I'm sure the staff -- staff person who wrote it works with me at Alston & Bird, so I'll go back and ask him, but I'm sure that it's probably, they froze it to freeze it, and some level of cross-subsidy apparently. I'm not sure what the congressional intent there was, but I think it was Senator Grassley's staff that did that provision. So I had totally forgotten we did it. That it was in the bill. It wasn't something that was widely discussed at all.

(5/15/2007 Scully Dep. at 365:22-367:10, Ex. 64.)

142. Prior to the reforms introduced by the MMA, the dispensing fee allowed for inhalation drugs under Medicare was \$5. (Ex. 212, 70 Fed. Reg. 70116, 70225 (Nov. 21, 2005).)

143. The MMA “[did] not specify a particular dispensing fee amount for inhalation drugs, nor . . . a method to determine a dispensing fee for inhalation drugs.” (Ex. 213, 69 Fed. Reg. 66236, 66339 (Nov. 15, 2004).)

144. CMS issued a proposed rule in August 2005, seeking comments on the proper dispensing fee for inhalation drugs. In its proposed rule, CMS stated: “The MMA changed the Medicare payment methodology for many Part B covered drugs. . . . Beginning with CY 2005, Medicare paid for nebulizer drugs at 106 percent of the ASP. The move to the ASP system represented a substantial reduction in reimbursement for the high volume nebulizer drugs.” (Ex. 214, 70 Fed. Reg. 45764, 45847 (Aug. 8, 2005).)

145. In response, CMS received a variety of comments, the majority of which cited a 2004 study by the American Association of Homecare (“AAH”), which surveyed 109 homecare

pharmacies between May and July 2004. The AAH study: (1) reported that dispensing fees were inadequately low and would lead 89% of suppliers to discontinue providing inhalation drugs to Medicare beneficiaries, and (2) suggested a dispensing fee of \$68.10 to cover the variety of costs associated with inhalation drugs. (Ex. 215 (Muse & Assocs., The Costs of Delivering Inhalation Drug Services to Medicare Beneficiaries).)

146. For 2004, CMS set an interim dispensing fee of \$57 for a 30-day prescription of inhalation drugs, and \$80 for a 90-day prescription. (Ex. 212, 70 Fed. Reg. 70116, 70225 (Nov. 21, 2005).)

147. CMS adopted a final rule in November 2005, setting the dispensing fee at \$33 (but keeping it at \$57 for the first 30-day period during which an individual uses an inhalation drug). (Ex. 212, 70 Fed. Reg. 70116, 70225 (Nov. 21, 2005).)

148. In its November 15, 2004 final rule (with comment period), “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005,” CMS stated:

Finally, we note that a key purpose of the MMA legislation was to eliminate the cross-subsidization of composite rate payments by drug payments. If the composite rate was inadequate before the MMA provision, it was inadequate for both hospital-based and independent facilities. As such, increasing the composite rate by relatively greater amounts for independent facilities than hospital-based facilities would place the latter facilities at a competitive disadvantage relative to the former facilities.

(Ex. 213, 69 Fed. Reg. 66236).)

149. In its November 21, 2005 final rule, “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B,” CMS stated:

Response: Although some commenters stated that the dispensing fee should account for drug acquisition costs in excess of the ASP+6 percent payment, we disagree. Section 1847A of the Act specifies that the Medicare payment for inhalation drugs is at 106 percent of the ASP. We believe the Congress established the ASP based payment for inhalation drugs and separate authority for dispensing of these drugs for good reason, namely to pay appropriately for each service and to eliminate cross subsidization of services. Similarly, we believe payment for nebulizer equipment is a distinct policy separate from the dispensing fee, and one should not cross subsidize the other. In establishing the dispensing fee of \$33 for a 30-day supply of inhalation drugs (and higher first month payment), we are focusing on what we believe is the appropriate scope and payment for the dispensing fee.

(Ex. 212, 70 Fed. Reg. 70116, 70231).)

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Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I, Brian J. Murray, an attorney, hereby certify that I caused a true and correct copy of the foregoing DEFENDANTS ABBOTT LABORATORIES, INC., DEY, INC., DEY, L.P., DEY L.P., INC., AND BOEHRINGER INGELHEIM ROXANE, INC. AND ROXANE LABORATORIES, INC.'S COMBINED LOCAL RULE 56.1 STATEMENT OF ADDITIONAL MATERIAL FACTS PERTINENT TO THE UNITED STATES' MOTIONS FOR PARTIAL SUMMARY JUDGMENT AGAINST DEFENDANTS to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 28th day of August, 2009.

/s/ Brian J. Murray  
Brian J. Murray